Description of document:	Food and Drug Administration (FDA) Information Disclosure Manual, February 1999
Requested date:	June 2012
Released date:	July 2012
Posted date:	30-July-2012
Source of document:	Food and Drug Administration Division of Freedom of Information Office of Shared Services Office of Public Information and Library Services 12420 Parklawn Drive ELEM-1029 Rockville, MD 20857 Fax: (301) 827-9267 Submit a FOIA request online
Note:	This document is obsolete and no longer represents FDA policy.

Information Disclosure Manual

DIVISION OF COMPLIANCE POLICY

OFFICE OF ENFORCEMENT

OFFICE OF REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

February 1999

Information Disclosure Manual

February 1999

Department of Health and Human Services
U.S. Food & Drug Administration
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy

FOREWORD

When asked to cite the most powerful force in the universe, Dr. Albert Einstein reportedly replied "compound interest." His point was that building wealth is fundamental to decisions reached in the markets, government and society. If you ask today's government managers to provide an opinion on the most powerful force in their universe, they may respond with "compound information."

We are in the Information Age and we can thank the computer revolution for bringing about our information revolution. These days, the task of mining the never-ending influx of FDA related information request is both challenging and mind boggling. The requests for information are increasing exponentially without concurrent increases in resources. In addition, the requests are becoming more sophisticated and complex. As any FDA employee knows, fulfilling these many requests can be a daunting task.

In order to assist our employees and provide them with appropriate guidance, we have developed an INFORMATION DISCLOSURE MANUAL. This manual contains information and agency procedures on disclosing both public and non-public information to the public, other federal governmental agencies, state and local governments as well as foreign governments. In addition, it also contains the Freedom of Information Act (FOIA), the Electronic Freedom of Information Act (E-FOIA), the Privacy Act, and associated regulations and preambles for ready reference. Further, the manual contains statements of national policy pertaining to FOIA disclosures.

One of the most important sections in the manual deals with frequently asked questions. The Questions and Answers section along with pertinent court cases on release of information provides an important practical insight into regulations surrounding the release of information.

This is our first attempt at compiling such a manual and as usual your comments and recommendations would be much appreciated. Please forward them to the Director, Division of Compliance Policy (HFC-230), 5600 Fishers Lane, Rockville, MD 20857.

Daniel L. Michels, Director
Office of Enforcement

Arvin P. Shroff, PhD, Deputy Director
Office of Enforcement

ACKNOWLEDGMENT

I wish to acknowledge the leadership and personal effort provided by Ms. Sharon M. Sheehan of the Office of Regulatory Affairs's (ORA) Division of Compliance Policy. She played a major role in preparing the Questions and Answers and the procedure sections on disclosure to federal, state, and foreign government agencies. She was instrumental in selecting most of the Manual's other sections and in coordinating much of the effort among the other contributors.

I want to acknowledge the special contributions of Ms. Betty Dorsey, Director, and Mr. Les Weinstein, Deputy Director, FDA's Freedom of Information (FOI) Staff, particularly for their review of the Questions and Answers section; Ms. Lori Knight, Esq., Office of Chief Counsel, for her review of the Questions and Answers section, and for her legal advice on FOI issues in general; and Mr. Donald Vasbinder of the Division of Compliance Policy for his contribution in electronic document policy, both in his contribution in the development of ORA Electronic FOIA Guidances and then in the creation of this Manual both as a paper copy and as an Internet document useful to both users.

In addition, there were a number of individuals who gave assistance in the development of this Manual. These individuals deserve recognition and are as follows:

- Ms. Barbara Rodgers, Ms. Terry Roseby, and Ms. Margarita Tello, of ORA's Division of Compliance Policy.
- Mr. Fred Sadler, Director, Access Litigation, FOI Staff and Michele Falchek, Senior Consumer Safety Officer, of the Center for Biologics Evaluation and Research
- Ms. Ann Curtsinger, Director, Freedom of Information Staff and Sherri Steinberg, Paralegal Specialist, of the Center for Devices and Radiological Health
- Ms. Carolann Hooton, Director of the Freedom of Information Staff, Center for Drug Evaluation and Research
- Ms. Marilyn Broderick, FOI Officer for the Center for Veterinary Medicine

Without the dedication and assistance of the above-mentioned persons, working as a team, this Manual would not have been possible.

David K. Haggard, Director
Division of Compliance Policy
ORA/Office of Enforcement

INTRODUCTION

PURPOSE

This manual contains information and agency procedures on disclosing both public and non-public information to the public, other federal governmental agencies, state and local governments and foreign governments. FDA employees asked to disclose non-public information are to follow the procedures set forth in this Manual and only authorized FDA employees should release non-public information.

This manual contains laws, regulations and internal guidance (procedures, answers to frequently asked questions). The guidance is intended to reflect our procedures and current thinking on our interpretations of laws and regulations pertaining to release of both public and non-public information. That guidance is not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended merely for internal guidance.

BACKGROUND

The procedures contained in this manual on disclosure of public and non-public information to the public, other federal agencies, state and local governments and foreign governments were part of FDA's Regulatory Procedures Manual (RPM), Chapter 8, and with this publication will be removed from the RPM.

CURRENT

This is the first edition of the FDA's Information Disclosure Manual (IDM).

CLEARANCE

The Division of Compliance Policy (HFC-230) within the Office of Enforcement has the responsibility for the IDM. The Division coordinates and obtains clearance as appropriate.

UPDATES

The content is always subject to revision and additions. All revisions and additions will be reflected in the electronic copy of the IDM on the Intranet (http://web.ora.fda.gov/oe/info_disclose/default.htm) and Internet sites (www.fda.gov).

DISTRIBUTION

FDA personnel:

Copies of the IDM may be obtained by contacting the Division of Compliance Policy (HFC-230).

Public:

The FDA Internet home page is www.fda.gov and this manual can be located through the links to the FOI icon on the home page.

FDA Information Disclosure Manual

Contents

SECTION I

Highlights of FOIA Provisions

HIGHLIGHTS OF THE FREEDOM OF INFORMATION ACT PROVISIONS

The following "Highlights" have been either excerpted from or are based on information in the Department of Justice's (DOJ) publication, "Freedom of Information Act Guide & Privacy Act Overview," 1997 Edition. The 1998 Edition may be found on the Internet at http://www.usdoj.gov/05publications.index.html or contact your Freedom of Information Act officer if you are interested in reading the DOJ overview. The DOJ Overview is a compilation of court opinions and that agency's interpretations of court opinions as a result of litigation of Freedom of Information Act issues. The following Highlights also contain comments relevant to FDA that were not taken from the DOJ Overview. In the following Highlights, not all court opinions from the publication are noted and not all citations to information based on court opinions are cited. These Highlights should be read in conjunction with the manual's Questions and Answers section, FDA's regulations at 21 C.F.R. § 20 et seq, and the DOJ's Overview.

INTRODUCTION

The Freedom of Information Act[1] (FOIA) generally provides that any person has a right, enforceable in court, of access to federal agency records, except to the extent that such records (or portions thereof) are protected from disclosure by one of nine exemptions or by one of three special law enforcement record exclusions. The nine exemptions of the FOIA provide the only bases for nondisclosure.[2]

The FOIA contains six subsections, the first two of which establish certain categories of information that must automatically be disclosed by federal agencies. Subsection (a)(1) of the FOIA[3] requires disclosure through publication in the Federal Register of information such as descriptions of agency organization, functions, procedures, substantive rules, and statements of general policy.[4] This requirement provides automatic public access to very basic information regarding the transaction of agency business.

Subsection (a)(2) of the FOIA[5] requires that certain types of records--final opinions rendered in the adjudication of cases, specific policy statements, certain administrative staff manuals and some records previously processed for disclosure under the Act--be routinely made "available for

---

[1]5 U.S.C. § 552 (1994), as amended by Electronic Freedom of Information Act Amendments of 1996, 5 U.S.C.A. § 552 (West Supp. 1997).

[2]See 5 U.S.C. § 552(d).

[3]Id. § 552(a)(1).

[4]See, e.g., Aulenback, Inc. v. Federal Highway Admin., 103 F.3d 156, 168 (D.C. Cir. 1997).

[5]5 U.S.C. § 552(a)(2).

public inspection and copying."[6] At the Food and Drug Administration (FDA), this is generally accomplished through FDA's two "reading rooms," and as a result of the Electronic FOIA Amendments [7] (hereafter referred to as "EFOIA"), many of the records in the reading rooms also are located in FDA's "electronic reading room."

Under subsection (a)(3) of the FOIA, all records not made available to the public under subsections (a)(1) or (a)(2), [8] or exempted from mandatory disclosure under subsection (b), or excluded under subsection (c), are subject to disclosure upon an agency's receipt of a proper access request from any person.

Subsection (c) of the FOIA,[9] establishes three special categories of law enforcement-related records that have been entirely excluded from the coverage of the FOIA so as to safeguard against certain types of harm.[10] The protection in subsection (c) permits an agency to respond to a request for such records as if the records in fact did not exist. An agency should not use this exclusion provision without first consulting with Department of Justice's Office of Information and Privacy.

Subsection (d) of the FOIA[11] makes clear that the FOIA was not intended to authorize any new withholding of information, including from Congress. Individual Members of Congress possess the same rights of access as those guaranteed to any person under subsection (a)(3). However, Congress as a body (or through its committee and subcommittees) cannot be denied access to information on the grounds of FOIA exemptions.[12] (However, FDA has, on occasion, withheld certain personal privacy and attorney-client or other deliberative process records from Congress.) Consult with an FDA FOIA Officer, a representative from FDA's Office of Legislative Affairs, or a FOIA attorney in the Office of Chief Counsel before responding to a request from Congress for information protected from disclosure by a FOIA exemption.

---

[6]Id. § 552(a)(2)(A)-(D).

[7]Pub. L. No. 104-231, 110 Stat. 3048.

[8]See 5 U.S.C. § 552(a)(3); United States Dep't of Justice v. Tax Analysts, 492 U.S.C. 136, 152 (1989); see also FOIA Updates, Winter 1995, at 2, Summer 1992, at 4, and Spring 1991, at 5. But see, FOIA Update, Winter 1997, at 3.

[9]Id. § 552(c).

[10]See generally, Attorney General's Memorandum on the 1986 Amendments to the Freedom of Information Act 18 (Dec. 1987).

[11]5 U.S.C. § 552(d).

[12]See FOIA Update, Winter 1984, at 3-4 ["OIP Guidance: Congressional Access Under FOIA") (citing, e.g., H.R. Rep. No. 89-1497, at 11-12 (1966)].

Subsection (e) of the FOIA[13] requires an annual report to Congress from each federal agency regarding its FOIA operations and an annual report from the Department of Justice regarding both FOIA litigation and the Department of Justice's efforts to encourage agency compliance with the FOIA.[14] Starting with the annual report for fiscal year 1998 (due by February 1, 1999), agencies will prepare these reports for submission to the Department of Justice, which in turn will make them available to the public through a single World Wide Web site.[15]

Subsection (f) of the FOIA[16] defines the term "agency" so that it subjects the records of nearly all executive branch entities to the FOIA and defines the term "record" to include information maintained in electronic format. Additionally, new subsection (g) of the FOIA[17] requires an agency to prepare a FOIA reference guide describing its information systems and its process of FOIA administration, which may assist potential FOIA requesters. (FDA's FOIA reference guide is found on the FDA Internet Page, **www.fda.gov.**

Freedom of Information Act Developments

The FOIA was originally enacted in 1966, and amended in 1974, 1976, 1978, 1984 (to repeal a section on expedited court-review), 1986 (which amended the FOIA to provide broader exemption protection for law enforcement information) and in October 1996 (EFOIA). The EFOIA addressed the subjects, among other things, of electronic records, as well as FOIA reading rooms and agency backlogs of FOIA requests. Some provisions of the EFOIA became effective as of March 31, 1997, others became effective on October 2, 1997, and some annual reporting provisions do not take effect until December 31, 1999.[18] (The Department of Justice, FDA's FOI Staff, and FDA's Office of Regulatory Affairs (ORA) have taken a number of steps to implement the provisions of EFOIA.[19])

---

[13]5 U.S.C. § 552(e).

[14]See, e.g., FOIA Update, Summer/Fall 1993, at 8-9 (describing range of the Department of Justice's Office of Information and Privacy activities, including its "ombudsman" function); see also FOIA Update, Fall 1987, at 2.

[15]See FOIA Update, Summer 1997, at 3-7.

[16]5 U.S.C. § 552(f).

[17]Id. § 552(g).

[18]See FOIA Update, Fall 1996.

[19]See FDA's March 28, 1997 memorandum and internal EFOIA guidance from James O'Hara, III, to Associate Commissioners and others, the October 23, 1997 ORA EFOIA Guidance #1, and the March 5, 1998 ORA EFOIA Guidance #2.

President Clinton's Memorandum; Attorney General Janet Reno's Memorandum about the "Foreseeable Harm Test"

In October 1993, President Clinton[20] issued a Memorandum that asked federal agencies to follow the "spirit" as well as the letter of the FOIA. Also in October 1993, Attorney General Janet Reno issued a Memorandum that described the FOIA's primary objective as maximum responsible disclosure of government information.[21] Attorney General Reno's Memorandum: (1) rescinded the Department of Justice's previous standard for the defense of FOIA litigation; (2) established a new "foreseeable harm" standard applicable to the use of FOIA exemptions both in litigation and at the administrative level; and (3) strongly encouraged the making of discretionary disclosures of exempt information "whenever possible under the Act."[22] Together, these Memoranda established a strong new spirit of openness in government under the FOIA.

FOIA READING ROOMS

Subsection (a)(2) of the FOIA provides for "reading room" access to records "available for public inspection and copying."[23] In addition to the three categories of records previously mentioned ("final opinions," policy statements, and staff manuals), the EFOIA Amendments in 1996 created a fourth category of "reading room" records and established a requirement for the electronic availability of "reading room" records, i.e., "electronic reading rooms."[24] The fourth category includes any records processed and disclosed in response to a FOIA request that "the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records."[25] (As of April 1997, ORA had determined that a record that had become or was expected to be the subject of three or more requests would fall into the new category.)

PROCEDURAL REQUIREMENTS

"Agency Records"

---

[20]See President Clinton's FOIA Memorandum, reprinted in FOIA Update, Summer/Fall 1993, at 3.

[21]Attorney General Janet Reno's FOIA Memorandum (October 4, 1993), reprinted in FOIA Update, Summer/Fall 1993, at 4-5; see also FOIA Update, Spring 1997, at 1.

[22]Id.; see also FOIA Update, Summer/Fall 1993, at 5.

[23]5 U.S.C. § 552(a)(2); see also FOIA Update, Winter 1997, at 4.

[24]Id. § 552(a)(2); see also FOIA Update, Fall 1996, at 1-2..

[25]See id. § 552(a)(2)(D); but see FOIA Update, Spring 1997, at 2.

The FOIA applies to "records" maintained by "agencies" within the executive branch of the federal government, including the Executive Office of the President and independent regulatory agencies.[26] The Supreme Court has articulated a basic, two-part test for determining what constitutes an "agency record" under the FOIA: "Agency records" are documents which are (1) either created or obtained by an agency, and (2) under agency control at the time of the FOIA request.[27] Certain records maintained by agency employees may qualify as "personal" rather than "agency records."[28]

Request Made by "Any Person"

A FOIA request can be made by "any person," as defined in 5 U.S.C. § 551(2) (1994), which encompasses individuals (including foreign citizens), partnerships, corporations, associations and foreign or domestic governments.[29] The statute specifically excludes federal agencies from the definition of a "person," but state agencies can make FOIA requests.[30] An exception to this standard is a person who flouts the law, such as a fugitive from justice or its agent. FOIA requesters do not have to explain or justify their requests.[31] The FOIA has been invoked successfully as a substitute for, or a supplement to, document discovery in the contexts of both civil and criminal litigation.

"Reasonably Described" Record

The FOIA specifies two requirements for requests: that they "reasonably describe" the records sought[32] and that they be made in accordance with an agency's published procedural

---

[26]See id. § 552(f).

[27]United States Dep't of Justice v. Tax Analysts, 492 U.S. 136, 144-45 (1989) (holding that court opinions in agency files are "agency records"); see Burka v. HHS, 87 F.3d 508, 515 (D.C. Cir. 1996) (finding data tapes created and possessed by contractor to be "agency records" because of the extensive supervision exercised by agency which evidenced "constructive control").

[28]Judicial Watch, Inc. v. Clinton, 880 F. Supp. 1, 11 (D.D.C. 1995) ("telephone logs, calendar markings, [and] personal staff notes" are not "agency records").

[29]See, e.g., Constangy, Brooks & Smith v. NLRB, 851 F.2d 839, 840 n. 2 (6th Cir. 1988) (recognizing standing of attorney to request documents on behalf of client).

[30]See, e.g., Massachusetts v. HHS, 727 F. Supp. 35, 35 (D. Mass. 1989); see also FOIA Update, Winter 1985, at 6.

[31]Durns v. Bureau of Prisons, 804 F.2d 701, 706 (D.C. Cir. 1986) ("Congress granted the scholar and the scoundrel equal rights of access to agency records.").

[32]5 U.S.C. § 552(a)(3)(A).

regulations.[33] One FOIA request was held invalid on the grounds that it required an agency's FOIA staff either to have "clairvoyant capabilities" to discover the requester's needs or to spend "countless numbers of personnel hours seeking needles in bureaucratic haystacks."[34]

The fact that a FOIA request is very broad or burdensome in its magnitude does not, in and of itself, entitled an agency to deny that request on the ground that it does not "reasonably describe" the records sought.

"Search" for Records

The EFOIA defines the term "search" as meaning "to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request."[35] The adequacy of the agency's search is determined by a test of "reasonableness," which may vary from case to case.[36] As a general rule, an agency must undertake a search that is "reasonably calculated" to locate the requested records, and if challenged in court, must be able to show what records were searched, by whom, and through what process.

Time to Respond

Until a FOIA request is properly received by the proper component of an agency, there is no obligation on the agency to search, to meet time deadlines, or to release documents.[37] If a requester fails to pay properly assessed search, review, and/or duplication fees, despite his prior commitment to pay that amount, the agency may refuse to process subsequent requests until the requester pays the outstanding balance.

The EFOIA increases the Act's basic time limit for agency responses, lengthening it from ten to twenty working days.[38] The time period for processing a FOIA request may be extended by ten working days by written notice to the requester explaining why an extension is needed and

---

[33]See id. § 552(a)(3)(B)

[34]Goldgar v. Office of Admin., 26 F.3d 32, 35 (5th Cir. 1994) (holding that agency not required to product information sought by requester--"the identity of the government agency that is reading his mind"--that does not exist in record form).

[35]5 U.S.C. § 552(a)(3)(D).

[36]Citizens Comm'n on Human Rights v. FDA, 45 F.3d 1325, 1328 (9th Cir. 1995) (determining that search was adequate when agency spent 140 hours reviewing relevant files, notwithstanding fact that agency was unable to locate 137 of 1000 volumes of records).

[37]See Brumley v. Department of Labor, 767 F.2d 444, 445 (8th Cir. 1985).

[38]5 U.S.C. § 552(a)(6)(A)(i)see also FOIA Update, Fall 1996, at 2, 10.

stating when a determination will be made on the request.[39] The FOIA provides for such extensions of initial time limits under "unusual circumstances," which are defined as (1) the need to search for and collect records from separate offices; (2) the need to examine a voluminous amount of records required by the request; and (3) the need to consult with another agency or agency component.[40] Determinations of administrative appeals are required to be made within twenty working days.[41]

Multi-Track Processing of Requests

The D.C. Circuit Court has approved the general practice of handling backlogged FOIA requests on a "first-in, first-out" basis.[42] Under the EFOIA, agencies are now authorized to promulgate regulations providing for "multitrack processing" of their FOIA requests, which allows for the processing of requests on a first-in, first-out basis within each track,[43] but permits agencies to respond to relatively simple requests more quickly than requests involving complex and/or voluminous records.[44] Also, the FOIA case law provides that if a FOIA requester can show an "exceptional need or urgency," his or her request may be "expedited" and processed out of sequence.[45] Expedited access has been granted when exceptional circumstances exist such as jeopardy to life or personal safety, or a threatened loss of substantial due process rights.

The EFOIA requires agencies to promulgate regulations providing for expedited processing of requests for records in cases in which the person requesting the records demonstrates a "compelling need," as defined by the EFOIA, or in any other case determined by the agency to be appropriate under its regulations.[46] "Compelling need" can be shown when failure to obtain

---

[39]Id. § 552(a)(6)(B)(i).

[40]Id. § 552(a)(6)(B)(iii).

[41]Id. § 552(a)(6)(A)(ii).

[42]Open America v. Watergate Special Prosecution Force, 547 F.2d 605, 614-16 (D.C. Cir. 1976) [citing 5 U.S.C. § 552 (a)(6)(C)].

[43]FDA plans to propose that each FDA component (Center, etc.), may choose to implement multi-track.

[44]5 U.S.C. § 552(a)(6)(D); see also FOIA Updates, Winter 1997, at 6, Fall 1996, at 10, and Summer 1997, at 3-7; see also Revised Department of Justice Freedom of Information Act Regulations, 62 Fed. Reg. 45,184 (1997) (to be codified at 28 C.F.R. pt. 16) (proposed Aug. 26, 1997).

[45]Open America, 547 F.2d at 616 (D.C. Cir. 1976); FOIA Updates, Summer 1983, at 3, and Summer 1992, at 5.

[46]5 U.S.C. § 552 (a)(6)(E); see also FOIA Update, Fall 1996, at 10.

records quickly "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual," or if the requester is a "persona primarily engaged in disseminating information" and can demonstrate that there is an "urgency to inform the public concerning actual or alleged Federal Government activity."[47] Agencies must act on requests for expedited access within ten calendar days of their receipt by the proper FOIA office.

Records Originating from Another Agency

When an agency locates records responsive to a FOIA request, it should determine whether any of those records, or information contained in those records, originated from another agency. An agency receiving such a request should consult with the agency whose information appears in responsive records, and, if the response to that consultation is delayed, notify the requester that a supplemental response will follow its completion.[48] When entire records originating with another agency are located, those records ordinarily should be referred to their originating agency for its direct response to that requester, and the requester should ordinarily be advised of such a referral. If an agency makes a referral to another agency in response to a FOIA request, the referring agency retains the responsibility of defending any agency action taken with respect to those records if the matter proceeds to litigation.[49]

"Reasonably segregable portion of a record"

The FOIA requires that "any reasonably segregable portion of a record" must be released after appropriate application of the nine exemptions.[50] If an agency determines that nonexempt material is so "inextricably intertwined" that disclosure of it would "leave only essentially meaningless words and phrases," the entire record may be withheld.[51]

Form and format of response

Under EFOIA, an agency must provide the requested record in any form or format requested by the person if the record is readily reproducible in that form or format, and make reasonable

---

[47]Id. § 552 (a)(6)(E)(v); see, e.g., Revised Department of Justice Freedom of Information Regulations, 62 Fed. Reg. at 45,187.

[48]See FOIA Updates, Summer 1991, at 3-4, and Summer/Fall 1993, at 6-8.

[49]See, e.g., Williams v. FBI, No. 92-5176, slip op. at 2 (D.C. Cir. May 7, 1993) (illustrating that, in litigation, referring agency is nevertheless required to justify withholding of record that was referred to another agency); see also, FOIA Update, Summer 1994, at 6.

[50]5 U.S.C. § 552(b) (sentence immediately following exemptions).

[51]Neufeld v. IRS, 646 F.2d 661, 663 (D.C. Cir. 1981).

efforts to maintain its records in forms or formats that are reproducible for such purposes.[52] These provisions require agencies to honor a requester's specific choice among existing forms of a requested record, assuming there is no exceptional difficulty in reproducing an existing record form, and to make "reasonable efforts" to disclose a record in a different form or format when that is requested and the record is "readily reproducible" in that new form or format.[53] Computer-stored records, whether stored in the central processing unit, on magnetic tape, or in some other form, are records for purposes of the FOIA. Courts have held that the FOIA "in no way contemplates that agencies, in providing information to the public, should invest in the most sophisticated and expensive form of technology."[54] However, the Department of Justice encourages agencies to use advanced technology to satisfy existing or potential FOIA demands most efficiently, including through "affirmative electronic disclosures."[55]

The EFOIA requires agencies to estimate the amount of information that has been deleted and to indicate that amount, wherever it is "technically feasible" to do so, at the point in the record where the deletion has been made.[56]

Denial of Request; "No Record" Responses

A decision to deny an initial request must inform the requester of the reasons for the denial and of the right to appeal.[57] Agencies also must include administrative appeal notifications in all of their "no record" responses to FOIA requesters.[58] Notifications to requesters should also contain information about when and where records will be made available; what fees, if any, must be paid prior to an agency response, what records are or are not responsive to the request; the date of receipt of the request or appeal, and the nature of the request or appeal, and when appropriate, the agency's interpretation of it.[59]

---

[52]5 U.S.C. § 552(a)(3)(B) see FOIA Update, Fall 1996, at 2.

[53]See FOIA Update, Winter 1997, at 5.

[54]Martin & Merrell, Inc. v. United States Customs Serv., 657 F. Supp. 733, 734 (S.D. Fla. 1986).

[55]See FOIA Update, Winter 1995, at 1-2.

[56]5 U.S.C. § 552 (b).

[57]Les Weinstein, Esq., Deputy Director, Freedom of Information Staff (HFI-30), is the FDA's Denials Officer.

[58]See Oglesby v. Department of the Army, No. 87-3349 (D.D.C. May 22, 1989), vacated & remanded, 920 F.2d 57, at 67 (D.C. Cir. 1990), summary judgment granted (D.D.C. Nov. 2 1994), aff'd in part, rev'd & remanded in part, 79 F.3d 1172, (D.C. Cir. 1996).

[59]See also FOIA Update, Spring 1994, at 1 (describing Department of Justice "FOIA Form Review" as example for other agencies to follow).

An agency should provide a FOIA request with the best copy available of a record, and should address any problem with the quality of its photocopy of a disclosed record in its correspondence.[60]

An agency's failure to comply with the time limits for either the initial request or the administrative appeal may be treated as a "constructive exhaustion" of administrative remedies, and a requester may immediately seek judicial review. The EFOIA excludes "a predictable agency workload" of FOIA requests as "exceptional circumstances...unless the agency demonstrates reasonable progress in reducing its backlog of pending requests."[61] A refusal by a requester "to reasonably modify the scope of a request or arrange for an alternative time frame for processing the request," may be used as evidence of "exceptional circumstances."[62]

Tangible, Evidentiary Objects

The FOIA applies to "records," not to tangible, evidentiary objects,[63] and a record may include a software program.[64] The EFOIA defines the term "record" as simply "includ[ing] any information that would be an agency record...when maintained by an agency in any format, including an electronic format."[65]

The FOIA does not provide for limited disclosure, e.g., providing exempt information to a requester and limiting his ability to further disclose it through a protective order.[66]

Requesters cannot compel agencies to make automatic releases of records as they are created,[67]

---

[60]See FOIA Update, Fall 1995, at 5.

[61]5 U.S.C. § 552 (a)(6)(C)(ii).

[62]Id. § 552 (a)(6)(C)(iii); see ORA EFOIA Guidance #2 about calling a requester to narrow a FOIA request (March 5, 1998).

[63]See Nichols v. United States, 325 F. Supp. 130, 135-36 (D. Kan. 1971) (holding that archival exhibits consisting of guns, bullets, and clothing pertaining to assassination of President Kennedy were not "records"); see also FOIA Update, Winter 1993, at 1.

[64]Cleary, Gottlieb, Steen & Hamilton v. HHS, 844 F. Supp. 770, at 782 (D.D.C. 1993).

[65]5 U.S.C. § 552(f)(2); see also FOIA Update, Fall 1996, at 2.

[66]Schiffer v. FBI, 78 F.3d 1405, 1410 (9th Cir. 1996) (reversing district court's conditional disclosure order).

[67]See Mandel Grunfeld & Herrick v. United States Customs Serv., 709 F.2d 41, 43 (11th Cir. 1983) (determining that plaintiff not entitled to automatic mailing of materials as they are

which means that requests cannot properly be made for "future" records not yet created.[68]

There is no damage remedy available to FOIA requesters for non-disclosure.[69] Generally, an agency is not required to respond to requests for records that fall within subsection (a)(2) of the Act and are already available for "reading room" inspection and copying. However, Congress has made it clear that the new reading category, created under the EFOIA, of FOIA-processed records would stand as an exception to the general rule and be subject to regulatory FOIA requests as well.[70]

EXEMPTION 1

Exemption 1 of the FOIA protects from disclosure national security information concerning the national defense or foreign policy, provided that it has been property classified in accordance with the substantive and procedural requirements of Executive Order 12, 958.[71],[72]

EXEMPTION 2

Exemption 2[73] of the FOIA exempts from mandatory disclosure records related solely to the internal personnel rules and practices of an agency.[74] Courts have interpreted the exemption to encompass two categories of information:

1. internal matters of a relatively trivial nature--sometimes referred to as "low 2" information; and

2. more substantial internal matters, the disclosure of which would risk circumvention of a

---

updated); see also, FOIA Update, Spring 1985, at 6.

[68]See Tuchincky, v. Selective Serv. Sys., 418 F.2d 155, 158 (7th Cir. 1969) (ordering that no automatic release required of material until request in hand).

[69]See, e.g., Schwarz v. United States Patent & Trademark Office, No. 95-5349, 1996 U.S. App. LEXIS 4609, at **2-3 (D.C. Cir. Feb. 22, 1996) (per curium).

[70]See FOIA Updates, Winter 1997, at 3, and Winter 1995, at 2.

[71]3 C.F.R. § 333 (1996), reprinted in abridged form in FOIA Update, Spring/Summer 1995, at 5-10.

[72]FDA does not use Exemption 1.

[73]FDA rarely uses Exemption 2.

[74]5 U.S.C. § 552(b)(2).

legal requirement--sometimes referred to as "high 2" information.[75]

However, if withholding the exempted record frustrates a legitimate public interest, the material should be released unless the government can show that disclosure would risk circumvention of a lawful agency regulation.[76]

"Low 2:" Trivial Matters

Exemption 2 of the FOIA protects from disclosure internal matters of a relatively trivial nature, based on the rationale that the task of processing and releasing some requested records would not be justified by any genuine public benefit. Therefore, this part of Exemption 2 is entirely subject to the policy of discretionary agency disclosure.[77] Exemption "low 2" has been construed by courts to protect from disclosure administrative data such as file numbers, mail routing stamps, initials, data processing notations, brief references to previous communications, and other similar administrative markings. However, Exemption "low 2" is not available to protect from disclosure, federal personnel lists.[78] Courts have focused on the lack of a "legitimate public interest" when applying "low 2" as to an agency's internal practices.[79] Nearly all administrative information covered solely by the "low 2" part of Exemption 2 should now be appropriate for discretionary disclosure under Attorney General Janet Reno's **"foreseeable harm"** standard.[80]

"High 2": Risk of Circumvention

The second category of information covered by Exemption 2 covers internal matters of a more substantial nature the disclosure of which would risk the circumvention of a statute or agency regulation. The majority of courts have held that Exemption 2 is applicable to internal administrative and personnel matters, including law enforcement manuals, to the extent that

---

[75]See FOIA Update, Summer 1989, at 3; see, e.g., Schiller v. NLRB, 964 F.2d 1205, 1207 (D.C. Cir. 1992).

[76]Founding Church of Scientology v. Smith, 721 F.2d 828, 830-31 n. 4 (D.C. Cir. 1983); Dirksen v. HHS, 803 F.2d 1456, 1458-59 (approving use of Exemption 2 to withhold Medicare claims-processing guidelines).

[77]See FOIA Update, Spring 1994, at 3 (that agencies should apply discretionary disclosure policy to the "low 2" aspect of Exemption 2).

[78]Schwaner v. Department of the Air Force, 898 F.2d 793, 797 (D.C. Cir. 1990); see FOIA Update Spring/Summer 1990, at 2.

[79]News Group Boston, Inc. v. National R.R. Passenger Corp., 799 F. Supp. 1264, 1268 (D. Mass. 1992), appeal dismissed, No. 92-2250 (1st Cir. Dec. 4, 1992).

[80]See FOIA Updates Summer/Fall 1993, at 4-5, and Spring 1994, at 3.

disclosure would risk circumvention of an agency regulation or statute or impede the effectiveness of an agency's law enforcement activities.[81] The Court of Appeals for the District of Columbia Circuit[82] established a two-part test for determining which sensitive materials are exempt from mandatory disclosure under Exemption 2. This test requires both:

1. that a requested document be "predominantly internal" and

2. that its disclosure "significantly risks circumvention of agency regulations or statutes."

Whether there is any public interest in disclosure is legally irrelevant under this "anti-circumvention" aspect of Exemption 2. The focus under "high 2" is that a FOIA disclosure should not "benefit those attempting to violate the law and avoid detection."[83] Exemption "high 2" rests upon a determination of "foreseeable harm."[84]

Courts have determined that law enforcement activities considered "internal" and protected from disclosure under "high 2" include, but are not limited to: general guidelines for conducting investigations, guidelines for conducting post-investigation litigation, guidelines for identifying law violators.[85] The courts have been reluctant, however, to extend Exemption 2 protection in the non-law enforcement context without first finding that records at issue are clearly predominantly internal. A record protected from disclosure under Exemption "high 2" must be reviewed to determine whether any "reasonably segregable" portion can be disclosed without harm to the agency.[86] Examples of information that have been found likely to result in harmful circumvention include, but are not limited to: information that would reveal the identities of informants or undercover agents, sensitive administrative notations in law enforcement files, security techniques used in prisons, and agency audit guidelines,[87] agency testing materials, and

---

[81]See Hardy v. Bureau of Alcohol, Tobacco & Firearms, 631 F.2d 653, 656 (9th Cir. 1980).

[82]Crooker v. Bureau of Alcohol, Tobacco & Firearms, 670 F.2d 1051, 1073-74 (D.C. Cir. 1981) (a case involving a law enforcement agents training manual).

[83]Id. at 1054.

[84]See FOIA Updates Summer/Fall 1993, at 4, and Spring 1994, at 3.

[85]Dirksen v. HHS, 803 F.2d 1456, 1458-59 (9th Cir. 1986) (affirming nondisclosure of claim-processing guidelines that could be used by health care providers to avoid audits).

[86]PHE, Inc. v. Department of Justice, No. 90-1461 (D.D.C. Jan. 31, 1991), summary affirmance denied, No. 91-5047 (D.C. Cir. Jan. 8, 1992), aff'd in part, remanded in part, 983 F.2d 248 (D.C. Cir. 1993).

[87]See, e.g., Archer v. HHS, 710 F. Supp. 909, 911 (S.D.N.Y. 1989) (Medicare reimbursement-review criteria ordered disclosed, but specific number that triggers audit protected).

records used to evaluate the credentials of federal job applicants.[88]

Many of the records protectible only on a "high 2" basis may be protectible also under Exemption 7(E). Therefore, an analysis to determine if the latter Exemption applies should be considered.

EXEMPTION 3

Exemption 3 of the FOIA incorporates the disclosure prohibitions that are contained in various other federal statutes. Exemption 3 allows the withholding of information prohibited from disclosure by another statute only if one of the following two requirements is met: the statute either "(A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B), establishes particular criteria for withholding or refers to particular types of matters to be withheld."[89] Exemption 3 generally is triggered only by federal statutes. Once the agency establishes that a statute is a *nondisclosure* statute and that it meets at least one of the requirements of Exemption 3, an agency must also establish that the *records* in question fall within the withholding provision of the nondisclosure statute.

Many statutes have been held to qualify as Exemption 3 statutes under the exemption's subpart (A), which encompasses statutes that *require* information to be withheld and leave the agency no discretion on the issue. An example is Rule 6(e) of the Federal Rules of Criminal Procedure, which regulates disclosure of matters occurring before a grand jury, and which satisfies the "statute" requirement of Exemption 3. As a general rule, an agency must be able to adequately document and support its argument that disclosure of the record would, in fact, reveal a secret aspect of the grand jury proceeding.[90]

Most Exemption 3 cases involve subpart (B), which encompasses statutes that either provide criteria for withholding information or refer to particular matters to be withheld either implicitly or explicitly.

Some statutes have been found to satisfy both Exemption 3 subparts (A) and (B). Also, Exemption 3 protection for information obtained by law enforcement agencies pursuant to court-ordered wiretaps has been recognized by district courts on a variety of bases, e.g., not distinguishing between the subparts. Courts have found that certain statutes fail to meet the requisites of either subpart (A) or (B). It also has been held that section 360j(h) of the Medical

---

[88]National Treasury Employees Union v. United States Customs Serv., 802 F.2d 525, at 528-29, 531 (D.C. Cir. 1986).

[89]5 U.S.C. § 552(b)(3).

[90]Isley v. Executive Office for United States Attorneys, No. 96-0123, slip op. at 2-4 (D.D.C. Mar. 27, 1997).

Device Amendments of 1976[91] is not an Exemption 3 statute because it does not specifically prohibit disclosure of records.[92]

Another Exemption 3 issue concerns the Trade Secrets Act,[93] which prohibits the unauthorized disclosure of certain commercial and financial information. Although the Supreme Court has declined to decide whether the Trade Secrets Act is an Exemption 3 statute,[94] most courts deciding the issue have held it is not.[95]

EXEMPTION 4

Exemption 4[96] of the FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential."[97] This exemption is designed to protect the interests of both the government and submitters of information. Its existence encourages submitters to *voluntarily* furnish useful commercial or financial information to the government and it correspondingly provides the government with an assurance that such information will be reliable. The exemption also gives protection to submitters who are *required* to furnish commercial or financial information to the government by safeguarding them from the competitive disadvantages that could result from disclosure.

The exemption covers two categories of information in federal agency records: (1) trade secrets, and (2) information which is (a) commercial or financial, and (b) obtained from a person, and (c) privileged or confidential.

Trade Secrets

The Court of Appeals for the District of Columbia Circuit in Public Citizen Health Research Group v. FDA[98] has adopted a narrow "common law" definition of the term "trade secret" that

---

[91]21 U.S.C. § 360j(h) (1994).

[92]See Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983).

[93]18 U.S.C. § 1905 (1994).

[94]Chrysler Corp. v. Brown, 441 U.S. 281, 319 n. 49 (1979).

[95]See, e.g., Anderson v. HHS, 907 F.2d 936, 949 (10th Cir. 1990); see FOIA Update, Summer 1985, at 3.

[96]See the "questions and answers" section of this document for examples of FDA records protected by Exemption 4.

[97]5 U.S.C. § 552(b)(4).

[98]704 F.2d 1280, 1288 (D.C. Cir. 1983).

differs from the broad definition used in the Restatement of Torts. In Public Citizen, the term "trade secret" was narrowly defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." This definition requires that there be a "direct relationship" between the trade secret and the productive process.[99]

Commercial or Financial Information

Most Exemption 4 cases focus on whether the information is commercial or financial information, obtained from a person, and privileged or confidential. If information relates to business or trade, courts generally consider it "commercial or financial."[100] The Court of Appeals for the District of Columbia Circuit has held that these terms should be given their "ordinary meanings" and rejected the argument that the term "commercial" be confined to records that "reveal basic operations," holding instead that records are commercial so long as the submitter has a "commercial interest" in them.[101] Similarly, a court has held that the term "commercial" includes anything "pertaining or relating to or dealing with commerce."[102] Examples of commercial or financial information, as determined by the courts, include: business sales statistics; research data; technical designs; customer and supplier lists; profit and loss data; overhead and operating costs, and information on financial conditions.[103]

Obtained from a "Person"

Exemption 4's second criteria, that the information be "obtained from a person," generally is easily met.

The term "person" refers to a wide range of entities, including an individual, partnership,

---

[99]Id.; see, e.g., Citizens Comm'n on Human Rights v. FDA, No. 92-5313, slip op. at 14 (C.D. Cal. May 10, 1993) ("information about how a pioneer drug product is formulated, chemically composed, manufactured, and quality controlled" held protectible as trade secrets), aff'd in part and remanded in part on other grounds, 45 F.3d 1325 (9th Cir. 1995).

[100]See, e.g., Cohen v. Kessler, No. 95-6140, slip op. at 9 (D.N.J. Nov. 25, 1996) (rat study's raw data" submitted to support application for approval of new animal drug held "clearly commercial in nature" because data was "valuable to [submitter's] business activities").

[101]Public Citizen, 704 F.2d, at 1290.

[102]American Airlines, Inc. v. National Mediation Bd., 588 F.2d 863, 870 (2d Cir. 1978).

[103]See, e.g., Landfair v. United States Dep't of the Army, 645 F. Supp. 325, 327 (D.D.C. 1986).

corporation, association,[104] or public or private organization other than an agency, associations, foreign government agencies or instrumentalities, state governments, Native American tribes or nations. However, information *generated by the federal government* is not "obtained from a person," and is, therefore, excluded from Exemption 4's coverage,[105] although it might be protected from disclosure under Exemption 5. However, records prepared by the federal government can come within Exemption 4 if they simply contain summaries or reformulations of information supplied by a source outside the government. Also, the fact that the federal government supervises or directs the preparation of information submitted by sources outside the government does not preclude that information from "being obtained by a person."[106]

"Confidential" Information

The third requirement of Exemption 4 is met if information is "privileged or confidential." The following chronology of court cases sets out the holdings that have established the tests to determine if information is "privileged or confidential." The outcome also depends on a determination of whether the information was voluntarily or involuntarily submitted to the agency. The Department of Justice's FOIA Update, Spring 1993, sets out a step-by-step analysis to determine if information submitted to the agency is "privileged or confidential."

1. National Parks & Conservation Ass'n v. Morton[107] (1974). The Court held that the test was an objective one. That is, the test was *not* whether: (1) the person who submitted the information would customarily disclose it to the public, *or* (2) the government promised that the information would not be released.[108] Rather, the Court held that the term "confidential" should be read to protect *both* the *government* and the *private* interests. The test is a two part (prong) test:

   A. The "impairment" prong: whether disclosure of the information is likely "to impair the Government's ability to obtain necessary information in the future," or

   B. The "competitive harm" prong: whether disclosure of the information is likely "to cause substantial harm to the competitive position of the person from whom the

[104]Goldstein v. HHS, No. 92-2013, slip op. at 4 (S.D. Fla. May 21, 1993).

[105]See Allnet Communication Servs. v. FCC, 800 F. Supp. 984, 988 (D.D.C. 1992).

[106]See Silverberg v. HHS, No. 89-2743, slip op. at 6 (D.D.C. June 14, 1991), appeal dismissed per stipulation, No. 91-5255 (D.C. Cir. Sept. 2, 1993).

[107]498 F.2d 765 (D.C. Cir. 1974).

[108]See Washington Post Co. v. HHS, 690 F.2d 252, 268 (D.C. Cir. 1982) (citing National Parks, 498 F.2d at 766).

information was obtained."[109] [In the aftermath of the Critical Mass case discussed below, the National Parks, "competitive harm" prong is used when the information was compelled (i.e., *not voluntary*) to be submitted to the agency.]

2. Critical Mass Energy Project v. NRC[110] (1992). The court confined the reach of National Parks and established a new standard to be used for determining whether information "voluntarily" submitted to the agency is "confidential." This case is the leading Exemption 4 case on the issue.

   As to the government's interest that is protected by nondisclosure, the court found that when information is compelled (i.e., *not voluntary*) to be submitted, the government interest that is protected is that of ensuring the continued reliability of the information. However, when the information is *voluntarily* submitted, the governmental interest protected by nondisclosure is that of ensuring the continued and full availability of the information.

   As to the submitter's interest, the court established two standards generally set out below:

   A. When information is *not voluntarily* submitted to the agency, the test is the "competitive harm" prong of National Parks, i.e., whether disclosure of the information is likely to cause substantial harm to the competitive position of the submitter.

   B. When information is *voluntarily* submitted to the agency, the test is whether the information is of a type that "would customarily not be released" to the public by the submitter.

The issue is whether the *submission* was voluntary, not whether the submitter voluntarily participated in the activity. Further, the mere existence of agency authority to require submission of information does not automatically mean that such a submission is "required." The agency must have actually exercised its authority in order for a submission to be considered "required."[111]

Most submissions considered by agencies under Exemption 4 will be considered to be "required" and so do not qualify for the broader protection afforded to "voluntary" submissions under

---

[109] National Parks, 498 F.2d at 770.

[110] 931 F.2d 939, 948 (D.C. Cir. 1991), vacated and remanded en banc granted, 942 F.2d 799 (D.C. Cir. 1991), grant of summary judgment to agency affirmed en banc, 975 F.2d 871 (D.C. Cir. 1992).

[111] See FOIA Update, Spring 1993, at 5.

Critical Mass.[112] When FDA conditioned its approval of a new drug on the manufacturer's submission of a post-marketing study, the protocol for that study (i.e., the design, hypothesis, and objectives) was deemed to be a required submission, even in the absence of a regulation requiring manufacturers to conduct that study, because submission for that particular manufacturer had been "necessary in order to obtain FDA approval" for the drug.[113]

The Department of Justice's FOIA Update, Spring 1993, p. 6, sets out an in-depth four-step analysis to determine whether commercial or financial information submitted to an agency is entitled to protection as "confidential" under Exemption 4. Set out below is an overview of the analysis.

Step 1. Verify that the threshold requirements of Exemption 4 are satisfied, i.e., that the information is "obtained from a person," and that it is "commercial or financial."

Step 2. Determine whether the information is "required" to be submitted to the government or whether the information was voluntarily submitted. To arrive at this determination, focus on two questions: (1) did the agency hold the legal authority to require that information submission, and (2) if so, did it in fact exercise that authority in obtaining that information? For purposes of this analysis, it does not matter that the underlying activity engaged in by the submitter is one in which participation is purely voluntary. The key question is whether those who choose to participate have information-submission requirements imposed upon them as a condition of their participation in that activity.

Step 3. For information deemed to be in the "required" category (i.e., was compelled to be submitted or was not voluntarily submitted), apply the National Parks tests to determine whether it is "confidential." In most cases under Exemption 4, the submitted information will be determined to have been required. An agency need not contact the submitter where the agency can determine on its own that disclosure would cause a submitter competitive harm under National Parks.

Step 4. For information deemed to be in the "voluntary" category, apply the Critical Mass test to determine whether it is "confidential." If the information is voluntarily submitted, it is eligible for protection as "confidential" information if it is of a kind that would customarily not be released to the public by the submitter. The court in Critical Mass, in creating this customary treatment standard, held that the test was dependent upon the treatment afforded the information by the individual submitter, not by the industry as a whole.[114] The agency has the burden of

---

[112]See FOIA Updates, Spring 1993, at 5, Summer/Fall 1993, at 4-5, and Spring 1994, at 3.

[113]Public Citizen Health Research Group v. FDA, 964 F. Supp. 413, 414 n. 1 (D.D.C. 1997).

[114]Critical Mass, 975 F.2d at 872, 878, 879, 880; see FOIA Update, Spring 1993, at 7.

> proving provider's custom. Courts have considered as persuasive, evidence such as the submitter's use of protective orders, markings on the documents, carefully guarding disclosure of the documents within the corporation, or strenuously and successfully opposed "production" of the documents during the discovery phase of litigation.
>
> An agency should be able to withhold information under the Critical Mass test without contacting the submitter wherever the agency already has a basis for being certain that the submitter does not customarily release any of that information to the public. Where an agency is uncertain, however, of the submitter's customary treatment of the information, the submitter should be requested to provide the agency with a description of its treatment of the information, including any disclosures that are customarily made and the conditions under which such disclosures occur.[115]

The passage of time, while sometimes eroding confidentiality, does not necessarily defeat Exemption 4 protection, provided that disclosure of the material would still be likely to cause substantial competitive harm.[116]

Types of competitive injury (under the competitive harm prong) that have been found by the courts include, but are not limited to, harms caused by disclosure of: detailed financial information such as a company's assets, liabilities, and net worth; a company's actual costs, break-even calculations, profits and profit rates; data describing a company's workforce which would reveal labor costs, profit margins and competitive vulnerability; a company's selling prices, purchase activity and freight charges; a company's purchase records, including prices paid for advertising; technical and commercial data, names of consultants and subcontractors, performance, cost and equipment information; shipper and importer names, type and quantity of freight hauled, routing systems, cost of raw materials, and information constituting the "bread and butter" of a manufacturing company; currently unannounced and future products, proprietary technical information, pricing strategy and subcontractor information; raw research data used to support a pharmaceutical drug's safety and effectiveness, information regarding an unapproved application to market the drug in a different manner, and sales and distribution data of a drug manufacturer; and technical proposals which are submitted, or could be used, in conjunction with offers on government contracts.

Several courts, including the D.C. Circuit, have held that the harms to the company flowing from "embarrassing" disclosures, or disclosures which could cause "customer or employee disgruntlement," are not cognizable under Exemption 4. (Moreover, such harms would not be

---

[115]See FOIA Update, Spring 1993, at 7.

[116]Burke Energy Corp. v. Department of Energy for the United States, 583 F. Supp. 507, 514 (D. Kan. 1984) (nine-year-old data protected).

cognizable under Exemption 6 either, because businesses have no "corporate privacy.")[117]

EXEMPTION 5

Exemption 5 of the FOIA protects "inter-agency or intra-agency memorandums or letters which would not be available by law to a party...in litigation with the agency."[118] The three most frequently invoked privileges that have been held to be incorporated into Exemption 5 are the deliberative process privilege, the attorney work-product privilege, and the attorney-client privilege. These privileges warrant close attention in connection with Attorney General Janet Reno's **"foreseeable harm"** standard.[119]

The courts have construed the scope of Exemption 5 to include documents generated outside of an agency if they are part of the agency's deliberative process, such as recommendations from Congress, advice from a state agency, documents originating with a court, or evaluative comments from a scientific journal's reviewers,[120] if such comments are regularly relied on by agency authors and supervisors in making the agency's decisions.

Deliberative Process Privilege

The most commonly invoked privilege incorporated within Exemption 5 is the deliberative process privilege, the general purpose of which is to "prevent injury to the quality of agency decisions."[121] The policy purposes are to: (1) encourage open, frank discussions on matters of policy between subordinates and superiors; (2) to protect against premature disclosure of proposed policies before they are finally adopted; and (3) to protect against public confusion that might result from disclosure of reasons and rationales that were not in fact ultimately the grounds for an agency's action.[122] The privilege protects not only records, but also the integrity of the deliberative process itself where the exposure of that process would result in harm.[123]

---

[117]See, e.g., National Parks, 547 F.2d at 685 n. 44.

[118]5 U.S.C. § 552(b)(5) (1994).

[119]See, e.g., FOIA Updates, Fall 1994, at 7, and Spring 1997 at 1.

[120]See Formaldehyde Inst. v. HHS, 889 F.2d 1118, 1123-24 (D.C. Cir. 1989) (citing CNA, 830 F.2d at 1161).

[121]NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151 (1975).

[122]See, e.g., Citizens Comm'n on Human Rights v. FDA, No. 92-5313, slip op. at 23 (C. D. Cal. May 10, 1993) (release of predecisional documents may confuse public about agency policy and procedure), aff'd in part & rev'd in part on other grounds, 45 F.3d 1325 (9th Cir. 1995).

[123]See, e.g., Schell v. HHS, 843 F.2d 933, 940 (6th Cir. 1988) ("Because Exemption 5 is concerned with protecting the deliberative process itself, courts now focus less on the material sought and more on the effect of the material's release.")

Even the mere status of an agency decision within an agency decisionmaking process may be protectible if the release of that information would have the effect of prematurely disclosing "the recommended outcome of the consultative process...as well as the source of any decision."[124] The predecisional character of a document is not altered by the fact that an agency has subsequently made a final decision or even has decided to not make a final decision.

Traditionally, the courts have established two requirements, both of which must be met for the deliberative process privilege to be invoked.[125] First, the communication must be predecisional, i.e., before adoption of an agency policy. Second, the communication must be deliberative, i.e. "a direct part of the deliberative process in that it makes recommendations or expresses opinions on legal or policy matters."[126] The burden is on the agency to show that the information in question satisfies both requirements.

As long as the document is generated as part of a continuing process of agency decisionmaking, Exemption 5 can be applicable. Postdecisional documents, on the other hand, generally implement a final policy or explain actions the agency already has taken, and those documents are not protected from disclosure by Exemption 5.[127] Portions of a postdecisional document that discuss predecision recommendations not expressly adopted by an agency can be protected. An agency should determine:

1. whether the document is a "final opinion,"[128]

2. the nature of the decisionmaking authority of the office or person who issued the document. For example, the courts look not only to the formal lines of authority, but often look "beneath the formal lines of authority to the reality of the decisionmaking process,"[129]

3. the direction in which the document flows along the decisionmaking chain, i.e., from

---

[124]Wolfe v. HHS, 839 F.2d 768, 775 (D.C. Cir. 1988) (en banc).

[125]See Mapother v. Department of Justice, 3 F.3d 1533, 1537 (D.C. Cir. 1993) ["The deliberative process privilege protects materials that are both predecisional and deliberative;" citing Petroleum Info. Corp. v. United States Dep't of the Interior, 976 F.2d 1429, 1434 (D.C. Cir. 1992).]

[126]Vaughn v. Rosen, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975).

[127]See, e.g., Sears, 421 U.S. at 153-154.

[128]5 U.S.C. § 552(a)(2)(A).

[129]Schlefer v. United States, 702 F.2d 233, 238 (D.C. Cir. 1983).

superior to subordinate, which is more likely to indicate a final decision, consider the "role," if any, that the record plays in the process of agency deliberations, [130] or

4. if the maker of the document adopted or incorporated it by reference.[131]

Ordinarily Exemption 5 is not applicable to purely factual matters or to factual portions of deliberative process documents, with the following two exceptions. First, courts generally allow agencies to withhold factual material in an otherwise deliberative document when the author of the document selects specific facts out of a larger group of facts and this act is deliberative in nature.[132] The second circumstance is when the information is so inextricably connected to the deliberative material that its disclosure would expose or cause harm to the agency's deliberations. Similarly, when factual or statistical information is actually an expression of deliberative communications, it may be withheld on the basis that to reveal that information would reveal the agency's deliberations.[133]

Courts have determined that Exemption 5 covers scientific reports that constitute the interpretation of technical data insofar as the opinion of an expert reflects the deliberative process of decision or policy making. Courts have also extended Exemption 5 to cover reformulations of computer programs that were used to analyze scientific data. Court have determined that the following documents have been protected from disclosure: advisory opinions, recommendations, deliberations comprising part of an agency's policy formulation process, and, although case law is not entirely settled on the point, briefing materials. Factual information within a deliberative document may be withheld when it is impossible to segregate the factual portions from the deliberative information.[134]

A draft of a document is likely to be protected by Exemption 5, regardless of whether it differs from its final version.[135] It appears that a "policy" focus has been emerging from the courts, and it looks at "whether the agency has...demonstrated the involvement of a policy judgment in the

---

[130]Formaldehyde, 889 F.2d at 1122.

[131]See, e.g., Afshar v. Department of State, 1 GDS ¶ 80,280 (D.D.C. 1980), aff'd in part, vacated in part, rev'd in part & remanded, 702 F.2d 1125, 1140 (D.C. Cir. 1983) (recommendation expressly adopted in postdecisional memorandum).

[132]Montrose Chemical Corp. v. Train, 491 F.2d 63, 71 (D.C. Cir. 1974).

[133]National Wildlife Fed'n v. United States Forest Serv., No. 86-1255, slip op. at 9 (D.D.C. Sept. 26, 1987).

[134]See FOIA Update, Summer/Fall 1993, at 10-11.

[135]See Mobil Oil Corp. V. EPA, 879 F.2d 698, 703 (9th Cir. 1989) (dicta); FOIA Update, Spring 1986, at 2.

decisional process relevant to the requested documents." [136]

Attorney Work-Product Privilege

The second privilege incorporated into Exemption 5 is the attorney work-product privilege, which courts have found protects, for example, documents and other memoranda prepared in anticipation of litigation if "litigation was a major factor" in the decision to create the document,[137] prepared for possible settlement of litigation, or prepared because of an agency decision to terminate litigation. Litigation need never have actually commenced.

Also, Rule 26(b)(3) of the Federal Rules of Civil Procedure allows the attorney work-product privilege to be used to protect documents prepared "by or for another party or by or for that other party's representative," and courts have extended the protection to materials prepared by nonattorneys who are supervised by attorneys.[138] The privilege has been held to remain applicable when the information has been shared with a party holding a common interest with the agency.[139]

The privilege remains applicable when the document has become the basis for a final agency decision.[140]

Factual work-product enjoys qualified immunity from civil discovery and such materials are discoverable only upon a showing that the party seeking discovery has a substantial need for the materials, which cannot be obtained elsewhere without undue hardship.

Attorney-Client Privilege

The third privilege incorporated into Exemption 5 concerns "confidential communications between an attorney and his client relating to a legal matter for which the client has sought

---

[136]Petroleum Information Corp. v. United States Department of the Interior, No. 89-3173 (D.D.C. Dec. 20, 1990) summary affirmance denied, No. 91-5059 (D.C. Cir. Dec. 4, 1991), aff'd, 976 F.2d 1429 (D.C. Cir. 1992), attorney's fees denied (D.D.C. Nov. 16, 1993).

[137]Wilson v. Department of Energy, No. 84-3163, slip op. at 7 n. 1 (D.D.C. Jan. 28, 1985).

[138]See, e.g., Davis v. FTC, No.96-CIV-9324, 1997 WL 73671, at *2 (S.D.N.Y. Feb. 20, 1997) (material prepared by economists for administrative hearing).

[139]Nishnic v. United States Dep't of Justice, No. 86-2602, slip op. at 10 (D.D.C. May 15, 1987) (documents shared with foreign nation).

[140]See Uribe v. Executive Office for United States Attorneys, No. 87-1836, slip op. at 5-6 (D.D.C. May 23, 1989).

professional advice."[141] Unlike the attorney work-product privilege, the availability of the attorney-client privilege is not limited to the context of (civil) litigation. The Supreme Court, in the civil discovery context, has emphasized the public policy underlying the attorney-client privilege, "that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer's being fully informed by the client."[142] The privilege encompasses confidential communications made to the attorney not only by decisionmaking personnel, but also by lower-echelon employees as well.[143]

EXEMPTION 6

Personal privacy interests are protected by two provisions of the FOIA, Exemptions 6 and 7(C) (described later in this publication). Exemption 6 relates to information in personnel and medical files and "similar files," when the disclosure of the information "would constitute a clearly unwarranted invasion of personal privacy."[144] Exemption 7(C) is limited to information compiled for law enforcement purposes.

To warrant protection from disclosure, the threshold is to first determine if the information falls within the category of personnel and medical files and similar files. The Supreme Court has made it clear that all information which "applies to a particular individual" meets the threshold requirement for Exemption 6 protection.[145] The D.C. Circuit Court reinforced this broad interpretation by subsequently holding that the tape recording of the last words of the space shuttle Challenger crew, contained personal information that was protected by Exemption 6.[146] That court also concluded that Exemption 6 is equally applicable to the "author" and the "subject" of a file.[147]

To qualify for protection under Exemption 6, information must be identifiable to a specific individual, unless that individual's identity cannot be determined after deletion of his name from the records.[148] Information pertaining to a large group of individuals is not identifiable to any

---

[141]Mead Data Cent., Inc. v. United States Dep't of the Air Force, 566 F.2d 242, 252 (D.C. Cir. 1977).

[142]Upjohn Co. v. United States, 449 U.S. 383, 389 (1981); see also FOIA Update, Spring 1985, at 3-4.

[143]Id. at 392-97.

[144]5 U.S.C. § 552(b)(6).

[145]United States Department of State v. Washington Post Co., 456 U.S. 595, 602 (1982).

[146]New York Times Co. v. NASA, 920 F.2d 1002, 1005 (D.C. Cir. 1990).

[147]Id. at 1007-08.

[148]See Chicago Tribune Co. v. HHS, No. 95 C 3917, 1997 U.S. Dist. LEXIS 2308, at **43-46

specific individual, unless that bit of information is attributable to members of the group as a whole.[149]

Once the threshold determination (personnel/medical/similar files) is made, the next determination is whether disclosure of the record would constitute a "clearly unwarranted invasion of personal privacy." This requires a balancing[150] "of the public's right to disclosure against the individual's right to privacy."[151] Courts have determined that, if no privacy interest is found, further analysis is unnecessary and the information must be disclosed. If a privacy interest is found, but there is no public interest, or if the privacy interest outweighs the public interest, the information should be protected. If the public interest outweighs the privacy interest, the information should be disclosed.

The Reporters Committee Decision

In 1989, the Supreme Court issued a landmark FOIA decision in United States Department of Justice v. Reporters Committee for Freedom of the Press,[152] in which it held that "rap sheets" (criminal history records) on individuals were entitled to protection under Exemption 7(C). The court set out five principles which govern the process by which determinations are made under both Exemptions 6 and 7(C) as described below:

1. Privacy interests can exist in personal information even though the information has been made available to the general public. The court established the **"practical obscurity"** standard, noting that if the information were "freely available" to the public, there would be no reason to invoke the FOIA to obtain access to the information.[153]

2. The identity of the FOIA requester cannot be taken into consideration in determining what should be released under the FOIA, except that the agency will not invoke an exemption when the interest to be protected is the requester's own interest.[154]

(N.D. Ill. Feb. 26, 1997) (magistrate's recommendation) (ordering release of breast cancer patient data forms that identify numbers only by 9-digit encoded "Study Numbers"), adopted (N.D. Ill. Mar. 28, 1997).

[149]See, e.g., Arieff v. United States Dep't of the Navy, 712 F.2d 1462, 1467-68 (D.C. Cir. 1983) (list of drugs ordered for use by some members of group of over 600 individuals).

[150]See FOIA Update, Spring 1989, at 7 (outlining mechanics of balancing process).

[151]Department of the Air Force v. Rose, 425 U.S. 352, 372 (1976).

[152]489 U.S. 749 (1989); see also FOIA Update, Spring 1989, at 3-6.

[153]Id. at 764.

[154]Id. at 771.

3. Rather than consider the purpose for which the request for information is made, the Court ruled that the determination "must turn on the nature of the requested document and its relationship to" the public interest generally.[155]

4. The scope of the public interest to be considered relates to the "core purpose of the FOIA," which is to "shed[] light on an agency's performance of its statutory duties."[156]

5. Agencies may engage in a categorical balancing in favor on nondisclosure. That is, it may conclude that a certain type of information always is protectible under an exemption without regard to individual circumstance.[157]

Privacy Considerations

The first step in the Exemption 6 balancing process is to determine whether public access to the information would violate a viable privacy interest of the individual who is the subject of such information.[158] The threat to privacy must be real and not speculative.[159] In some cases, the disclosure of information may involve little or no invasion of privacy because no expectation of privacy exists.[160] For example, civilian federal employees have no expectation of privacy regarding their names, titles, grades, salaries and duty stations. Also, there is no expectation of privacy if the information is widely available within the public domain, or if the individual made the information public himself or herself. However, if the information was made, at some time or place, available to the public, but is now "hard-to-obtain information," the individual to whom it pertains may have a privacy interest in maintaining "**practical obscurity**."[161]
Courts have determined that FOIA requesters, except when they are making first-party requests, do not ordinarily expect that their names will be kept private. Personal information about the FOIA requesters, however, such as home addresses and home telephone numbers should not be disclosed.[162] The identities of first-party requesters under the Privacy Act of 1974[163] should be

---

[155]Id. at 772.

[156]Id. at 773.

[157]Id. at 780; see also FOIA Update, Spring 1996, at 3-4.

[158]See Schell v. HHS, 843 F.2d at 938.

[159]See Department of the Air Force v. Rose, 425 U.S. at 380 n. 19.

[160]See, e.g., National W. Life Ins. Co. v. United States, 512 F. Supp. 454, 461 (N.D. Tex. 1980).

[161]Reporters Comm., 489 U.S. at 780.

[162]See FOIA Update, Winter 1985.

protected because, unlike information requested under the FOIA, the expectation of privacy can fairly be inferred from the personal nature of the records involved in those requests. The identities of individuals who write to the government expressing personal opinions should be withheld, but not necessarily the substance of their letters.[164] Corporations or business associations do not possess protectible privacy interests, however, a closely held corporation (i.e., when the corporation and the individual are the same) might have an expectation of privacy, depending on the circumstances.[165] The majority rule is that death extinguishes the privacy rights of individuals. However, particularly sensitive, often graphic, personal details about the circumstances surrounding an individual's death may be withheld when necessary to protect the privacy interests of the surviving family members,[166] or if disclosure of the information would cause "disruption of their [family members] peace of minds."[167]

Although one's status as a public figure might in some circumstances tip the balance in favor of disclosure, a public figure does not, by virtue of his or her status, forfeit all rights of privacy.[168] Individuals who testify at criminal trials do not forfeit their rights to privacy except on those very matters that become part of the public record.[169] Individuals who provide law enforcement agencies with reports of illegal conduct have privacy interests, particularly when such persons reasonably fear reprisals for their assistance.[170]

Also note that, unlike under the Privacy Act, foreign nationals are entitled to the same privacy

---

[163]5 U.S.C. § 552(a) (1994) (amended 1996).

[164]See Strout v. United States Parole Comm'n., 40 F.3d 136, 139 (6th Cir. 1994) (articulating public policy against disclosure of names and addresses of people who write Parole Commission opposing convict's parole).

[165]See, e.g., Ackerson & Bishop Chartered v. USDA, No. 92-1068 , slip op. at 1 (D.D.C. July 15, 1992) (commercial mushroom growers operating under individual names have no expectation of privacy).

[166]Bowen v. FDA, 925 F.2d 1225, 1228 (9th Cir. 1991) (affirming nondisclosure of autopsy reports of individuals killed by cyanide-contaminated products).

[167]New York Times Co. v. NASA, 782 F. Supp. 628, 631-32 (D.D.C. 1991) (withholding audiotape of voices of Challenger astronauts recorded immediately before their deaths).

[168]Fund for Constitutional Gov't v. National Archives & Records Serv., 656 F.2d 856, 865 (D.C. Cir. 1981) [Exemption 7(C)].

[169]Brown v. FBI, 658 F.2d 71, 75 (2d Cir. 1981).

[170]See McCutcheon v. HHS, 30 F.3d 183, 189 (D.C. Cir. 1994) (privacy interest of "whistle blower").

rights under the FOIA as are U. S. citizens.[171]

Courts have held that the FOIA does not require an agency "to track down an individual about whom another has requested information merely to obtain the former's permission to comply with the request."[172] However, several pre-Reporters Committee cases held that the fact that a requester has not submitted authorizations from third parties may not in and of itself justify the automatic withholding of all information regarding those third parties on privacy grounds.[173]

Factoring in the Public Interest

The burden of establishing that disclosure would serve the public interest is on the requester.[174] Information that does not directly reveal the operations or activities of the federal government[175] "falls outside the ambit of the public interest that the FOIA was enacted to serve."[176] If an asserted public interest is found to qualify under this narrow standard, it then must be accorded some measure of value so that it can be weighed against the threat to privacy.[177]

Information which would inform the public of violations of the public trust has a strong public interest and is accorded great weight in the balancing process. Courts have held that, as a general rule, proven wrongdoing of a serious and intentional nature by a high-level government official is of sufficient public interest to outweigh the privacy interest of the official. Whereas, less serious misconduct by a low-level employee generally is not of sufficient public interest to outweigh the privacy interest of the employee.

Finally, if alternative, less intrusive means are available to obtain information that would serve the public interest, there is less need to require disclosure of information that would cause a substantial invasion of an individual's privacy.

Balancing Process; "Glomarization"

---

[171]See Shaw v. United States Dep't of State, 559 F. Supp. 1053, 1067 (D.D.C. 1983); FOIA Update, Summer 1985, at 5.

[172]Blakely v. Department of Justice, 549 F. Supp. 362, 365 (D.D.C. 1982) [Exemption 7(C)].

[173]See Ray v. United States Dep't of Justice, No. 86-5972, slip op. at 1 (6th Cir. June 22, 1987) [Exemption 7(C)].

[174]See Carter v. United States Dep't of Commerce, 830 F.2d 388, 391 nn. 8 and 13 (D.C. Cir. 1987); see also FOIA Update, Spring 1989, n. 7.

[175]See Landano v. United States Dep't of Justice, 956 F.2d 422, 430 (3d Cir.)

[176]Reporters Committee, 489 U.S. at 775.

[177]See, e.g., Rose, 425 U.S. at 372.

The agency must weigh the public interest in disclosure against the privacy interest of the individual to determine whether the requested information is exempt from disclosure. The courts have protected the personal, intimate details of an individual's life, protecting information which, if disclosed, is likely to cause the individual involved personal distress or embarrassment. Courts regularly uphold the nondisclosure of information including, but not limited to, marital status, legitimacy of children, welfare payments, family fights and reputation, medical condition, date of birth, religious affiliation, citizenship data, social security numbers, criminal history records ("rap sheets"), incarceration of United States citizens in foreign prisons, sexual inclinations or associations, financial status, and details of an employee's outstanding performance evaluation (on the basis that it may embarrass the employee), identities of mid- and low-level federal employees accused of misconduct as well as to the details and results of any internal investigations into such allegations of impropriety.[178]

In applying Exemption 6, all reasonably segregable, nonexempt portions of requested records must be released. In some situations the deletion of personal identifying information may not be adequate to provide necessary privacy protection.[179] The key consideration should be whether the information in question can be disclosed without foreseeably harming the privacy interests of the individual involved.[180] When the information in question concerns a small group of individuals who are known to each other and easily identifiable from the details contained in the information, redaction might not adequately protect privacy interests.[181]
When the records about an individual are particularly sensitive, it may be necessary to follow **"Glomarization"** procedures to protect the targeted individual's privacy. If a request is formulated in such a way that even acknowledgment of the existence of responsive records would cause harm, then the subject's privacy can be protected only by refusing to confirm or deny that responsive records exist,[182] e.g., records about an employee's participation in an Employee Assistance Program.

---

[178]See, e.g., Stern v. FBI, 737 F.2d 84, 94 (D. C. Cir. 1984) (protecting identities of mid-level employees censured for negligence, but requiring disclosure of identity of high-level employee found guilty of serious, intentional misconduct [Exemption 7(C)].

[179]See, e.g., Rose, 425 U.S. at 381.

[180]Accord Attorney General's Memorandum for Heads of Departments and Agencies regarding the Freedom of Information Act (Oct. 4, 1993), reprinted in FOIA Update, Summer/Fall 1993, at 4-5 (establishing "foreseeable harm" standard).

[181]See, e.g., Alirez v. NLRB, 676 F.2d 423, 428 (10th Cir. 1982) (mere deletion of names and other identifying data concerning small group of coworkers inadequate to protect them from embarrassment or reprisals because requester could still possibly identify individuals).

[182]See FOIA Update, Spring 1986, at 2.

EXEMPTION 7

Exemption 7 of the FOIA, as amended, protects from disclosure "records or information compiled for law enforcement purposes," but only to the extent that the production of such law enforcement records or information:

(A) could reasonably be expected to interfere with enforcement proceedings,
(B) would deprive a person of a right to a fair trial or an impartial adjudication,
(C) could reasonably be expected to constitute an unwarranted invasion of personal privacy,
(D) could reasonably be expected to disclose the identity of a confidential source, including a state, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source,
(E) would disclose techniques or procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or
(F) could reasonably be expected to endanger the life or physical safety of any individual.[183]

The protections of Exemption 7's six subparts are available to all records or information that have been compiled for "law enforcement purposes."[184] The "law" to be enforced within the meaning of the term "law enforcement purposes" includes both civil and criminal statutes, as well as those statutes authorizing administrative (i.e., regulatory) proceedings.[185] Exemption 7 applies to records compiled to enforce state and foreign laws. If the agency lacks the authority to pursue a particular law enforcement matter, Exemption 7 protection may not be afforded.[186] Finally, the full effects of the 1986 FOIA amendments on the parameters of Exemption 7's threshold still remain to be seen. For the principal federal law enforcement agencies, this means that any record previously not considered covered by Exemption 7, due solely to its noninvestigatory character, likely is sufficiently related to the agency's general law enforcement mission that it can

---

[183]5 U.S.C. § 552(b)(7) (1994).

[184]See Attorney General's Memorandum on the 1986 Amendments to the Freedom of Information Act at 7 (Dec. 1987) [hereinafter Attorney General's 1986 Amendments Memorandum].

[185]See, e.g., Straughter v. HHS, No. 94-0567, slip op. at 4 (S.D. W. Va. Mar. 31, 1995).

[186]See, e.g., Weissman v. CIA, 565 F. 2d 692, 696 (D.C. Cir. 1977) (ruling that CIA's "full background check within the United States of a citizen who never had any relationship with the CIA is not authorized and the law enforcement exemption is accordingly unavailable.")

be considered for Exemption 7 protection.[187]

Exemption 7(A)

Exemption 7(A) authorizes the withholding of "records or information compiled for law enforcement purposes, but only to the extent that production of such law enforcement records or information...could reasonably be expected to interfere with enforcement proceedings." Determining the applicability of Exemption 7(A)[188] requires a two-step analysis focusing on:

1. whether a law enforcement proceeding is pending or prospective, and

2. whether release of information about it could reasonably be expected to cause some articulable harm.[189]

Legislative history, as well as judicial interpretations of congressional intent of this subsection, makes clear that Exemption 7(A) was not intended to "endlessly protect material simply because it [is] in an investigatory file."[190] Exemption 7(A) may be invoked so long as the proceeding remains pending, or is regarded as prospective,[191] or as preventative. Even after an investigation is closed, the exemption may be applicable if disclosure could be expected to interfere with a related, pending enforcement proceeding,[192] to deter witness cooperation, or to prevent the government from obtaining data in the future.

Exemption 7(A) ordinarily will not afford protection when the target of the investigation has possession of or submitted the information in question.[193] However, courts will protect such

---

[187]See PHE, 983 F.2d at 249, 251, 253.

[188]See the "questions and answers" part of this document for examples of FDA's "law enforcement records."

[189]See, e.g., Campbell v. HHS, 682 F.2d 256, 259 (D.C. Cir. 1982) (agency must demonstrate interference with pending enforcement proceeding).

[190]See, e.g., NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214, 232 (1978).

[191]See, e.g., Marzen v. HHS, 632 F. Supp. 785, 805 (N.D. Ill. 1986) [Exemption 7(A) prohibits disclosure of law enforcement records when release "would interfere with enforcement proceedings, pending, contemplated, or in the future."), aff'd, 825 F.2d 1148 (7th Cir. 1987).

[192]See also FOIA Update, Spring 1984, at 6.

[193]See also Oncology Servs. Corp. v. NRC, No. 93-0939, slip op. at 17 (W.D. Pa. Feb. 7, 1994) (agency may not categorically withhold transcribed interviews which were conducted in presence of requester's attorney and individuals consented to release.)

information if an agency can demonstrate that its "selectivity of recording" information provided by the target would suggest the nature and scope of the investigation, or that the category of documents, if disclosed, would cause interference.[194]

It has been held that an agency is not expected to monitor the investigation after completion of the FOIA administrative process and to process the documents once the investigation is closed.[195]

Agencies should be aware of the **"(c)(1) exclusion"**[196] (explained in more detail later in this publication) which applies to situations in which the very fact of a criminal investigation's existence is as yet unknown to the investigation's subject, and disclosure of the existence of the investigation (which would be revealed by any acknowledgment of the existence of responsive records) could reasonably be expected to interfere with enforcement proceedings. Under these circumstances, an agency may treat the records as not subject to the requirements of the FOIA.

Exemption 7(B)

Exemption 7(B) protects "records or information compiled for law enforcement purposes [the disclosure of which] would deprive a person of a right to a fair trial or an impartial adjudication."[197] The purpose of this exemption is to prevent prejudicial pretrial publicity that could impair a court proceeding. This exemption is rarely invoked.

Exemption 7(C)

Exemption 7(C) provides protection for personal information in law enforcement records. This exemption is the law enforcement counterpart to Exemption 6 (described previously), providing protection for law enforcement information the disclosure of which "could reasonably be expected to constitute an unwarranted invasion of personal privacy."[198] Exemption 6 routinely requires an identification and balancing of the relevant privacy and public interests. Exemption 7(C), however, can be even more "categorized" in its application.[199] Exemption 7(C) establishes a lesser burden of proof, than Exemption 6 establishes, to justify withholding information. This is demonstrated by the omission of the word "clearly" from the language of Exemption 7(C) (as opposed to Exemption 6). Also, the risk-of-harm standard is lower in Exemption 7(C) than in Exemption 6, as evidenced by the language of "could reasonably be expected to" [harm] rather

---

[194]See Linsteadt v. IRS, 729 F.2d 998, 1004-05 (5th Cir. 1984).

[195]See Church of Scientology Int'l v. IRS, 816 F. Supp.1138, 1157 (W.D. Tex. 1993).

[196]5 U.S.C. § 552(c)(1).

[197]Id. § 552(b)(7)(B).

[198]Id. § 552(b)(7)(C).

[199]See SafeCard Services v. SEC, 926 F.2d 1197, 1206 (D.C. Cir. 1991).

than "would."

Both Exemptions 6 and 7(C) undergo balancing tests (individual's privacy interest vs. public's interest in disclosure). Exemption 7(C) has been applied by the courts to withhold references to persons who are not targets of investigations and who were merely mentioned in law enforcement files, as well as to persons of "investigatory interest" to a criminal law enforcement agency.[200] The identities of federal, state, and local law enforcement personnel referenced in investigatory files are also routinely withheld.[201] The majority of courts have held the identities of law enforcement personnel exempt pursuant to Exemption 7(C).[202] All courts of appeals to have addressed the issue have found protectible privacy interests--in conjunction with or in lieu of protection under Exemption 7(D)--in the identities of individuals who provide information to law enforcement agencies.[203] The names of witnesses, their home and business addresses, and their telephone numbers, and the identities of informants (even when it was shown that the "information provided to law enforcement agencies was knowingly false"[204]) have been held by courts to be properly protectible under Exemption 7(C).

Under the Reporters Committee **"practical obscurity"** standard, trial testimony should not ordinarily diminish Exemption 7(C) protection. If a person who actually testifies retains a substantial privacy interest, the privacy of someone who is identified only as a potential witness likewise should be preserved.[205] Also, courts have recognized that the passage of time will not ordinarily diminish the applicability of Exemption 7(C).

An individual's Exemption 7(C) privacy interest is not extinguished merely because a requester might on his own be able to "piece together" the identities of third parties whose names have been deleted.[206] Nor do persons mentioned in law enforcement records lose all their rights to privacy merely because their names have been disclosed.[207]

---

[200]See, e.g., Reporters Committee, 489 U.S. at 779.

[201]Nix v. United States Dep't. of Justice, 572 F.2d 998, 1006 (4th Cir. 1978); see FOIA Update, Spring 1984, at 5.

[202]See, e.g., Manna v. United States Dep't of Justice, 51 F.3d 1158, 1166 (3d Cir. 1995).

[203]See, e.g., Beard v. Espy, No. 94-16748, 1995 U.S. App. LEXIS 38269 at *2 (9th Cir. Dec. 11, 1995) (protecting complaint letter).

[204]Gabrielli v. United States Dep't of Justice, 594 F. Supp. 309, 313 (N.D. N.Y. 1984).

[205]See Watson v. United States Dep't of Justice, 799 F. Supp. 193, 196 (D.D.C. 1992) (identities of potential witnesses protectible).

[206]See Weisberg v. United States Dep't of Justice, 745 F.2d 1476, 1491 (D.C. Cir. 1984).

[207]See, e.g., Schiffer v. United States Dep't of Justice, No. C93-0995 (N.D. Cal. Jan. 10,

In SafeCard, the plaintiff sought information pertaining to an SEC investigation of manipulation of SafeCard stock, including "names and addresses of third parties mentioned in witness interviews, of customers listed in stock transaction records obtained from investment companies, and of persons in correspondence with the SEC."[208] The D.C. Circuit Court held that "unless access to the names and addresses of private individuals appearing in files within the ambit of Exemption 7(C) is necessary in order to confirm or refute compelling evidence that the agency is engaged in illegal activity, such information is [categorically] exempt from disclosure.[209] However, agencies should be sure to redact their law enforcement records so that only identifying information is withheld under Exemption 7(C).

Except when the third-party subject, who is the target of a FOIA request and is named in an investigatory record, is *deceased or provides a written waiver of his privacy rights*, law enforcement agencies ordinarily "**Glomarize**" such third-party requests--refusing either to confirm or deny the existence of responsive records--in order to protect the individual's privacy interests.[210] In employing privacy "**Glomarization**," agencies must be careful to use it only to the extent that it is warranted by the terms of the particular FOIA request. Agencies should follow the general rules set out below when determining what part of the record should be "Glomarized."

1. FOIA requests that merely seek law enforcement records pertaining to a named individual, without any elaboration, can be given a standard "Glomarization" response;

2. any request that is specifically and exclusively directed to an agency's non-law enforcement files (e.g., one aimed at personnel files only) should receive purely conventional treatment, without "Glomarization"; and

3. FOIA requests that do more than simply seek law enforcement records on a named individual (e.g., ones that encompass personnel or possible administrative files as well) must be bifurcated for conventional as well as "Glomarization" treatment.[211]

EXEMPTION 7(D)

1994), rev'd sub nom. Schiffer v. FBI, 78 F.3d 1405, 1410-11 (9th Cir. 1996).

[208]SafeCard, 926 F.2d at 1205.

[209]Id. at 1206.

[210]See, e.g., Antonelli v. FBI, 721 F.2d 615, 617 (7th Cir. 1983), cert. denied, 467 U. S. 1210 (1984).

[211]Accord FOIA Update, Spring 1996, at 3-4.

Exemption 7(D) of the FOIA protects against disclosure of information pertaining to confidential sources. Exemption 7(D) provides protection for "records or information compiled for law enforcement purposes [which] could reasonably be expected to disclose the identity of a confidential source--including a state, local or foreign agency or authority or any private institution which furnished information on a confidential basis--and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source."[212]

Historically, the term "source" has been interpreted by courts to include a wide variety of individuals and institutions that are not necessarily specified on the face of the statute--such as crime victims, citizens providing unsolicited allegations of misconduct, citizens responding to inquiries from law enforcement agencies, private employees responding to OSHA investigators about the circumstances of an industrial accident, employees providing information about their employers, prisoners, mental health care facilities, medical personnel, commercial or financial institutions, state and local law enforcement agencies, and foreign law enforcement agencies. By contrast, neither federal law enforcement agencies nor federal employees when acting in their official capacities should receive any "confidential source" protection.[213]

The Supreme Court in United States Department of Justice v. Landano[214] ruled that source confidentiality must be determined on a case-by-case basis, noting that a presumption of confidentiality should not be applied automatically to cooperating law enforcement agencies. Accordingly, federal agencies now have the burden of determining and proving through the use of detailed affidavits in litigation that cooperating law enforcement agencies have provided information under either an express or an implied promise of confidentiality.[215]

Agencies should consider Attorney General Janet Reno's "**foreseeable harm**" standard, which promotes the withholding of information only to the extent necessary to prevent source identification.[216]

---

[212]5 U.S.C. § 552(b)(7)(D).

[213]See also FOIA Update, Spring 1984, at 7.

[214]508 U.S. 165, 179-180 (1993).

[215]See, e.g., Beard v. United States Dep't of Justice, 917 F. Supp. 61, 63 (D.D.C. 1996) (finding implied confidentiality when agency attested that "[the FBI requested permission from the [local law enforcement agency] to release the information [and the request was denied]); see also FOIA Update, Summer/Fall 1993, at 10.

[216]See FOIA Updates, Summer/Fall 1993, and Spring 1997 (citing Department of Justice discussion of Attorney General Janet Reno's "foreseeable harm" standard).

The first clause of Exemption 7(D), with respect to civil or criminal law enforcement records, focuses upon the *identity* of a confidential source, rather than the *information* furnished by the source. Congressional intent was to protect the *identity* of anyone who provided information to a government agency in confidence.[217] The first clause of Exemption 7 protects "both the *identity* of the informer and *information* which might reasonably be found to lead to disclosure of such *identity*." (Emphasis added.)[218] Therefore, courts have recognized that the first clause of Exemption 7(D) safeguards not only obviously identifying information as an informant's name and address, but also information which would "tend to reveal" the source's identity,[219] e.g., the name of a third party who acted as an intermediary for the source.

When circumstances warrant, a law enforcement agency may employ a "**Glomar**" response. A criminal law enforcement agency may entirely exclude records from the FOIA under a "**(c)(2) exclusion**,"[220] to avoid divulging the existence of a source relationship. Also, *information* provided by a source may be withheld under the first clause of Exemption 7(D) if disclosure of that information would permit the "linking" of a source to specific source-provided material.

Informants' identities are protected wherever they have provided information under either an express promise of confidentiality[221] or under "circumstances from which such an assurance could be reasonably inferred."[222] A difficult issue under Exemption 7(D) involves the circumstances under which an expectation of confidentiality can be shown to have been implied. An implicit promise of confidentiality may be discerned from the inherent sensitivity of both criminal and civil investigations.[223] Agencies seeking to invoke Exemption 7(D) must prove expectations of confidentiality based upon the circumstances of each case. Law enforcement agencies, to determine "implied confidentiality," will have to address both the "nature of the crime" and "the source's relation to it."[224] Courts have recognized as a key consideration (for implied confidentiality) the potential for retaliation against the source.[225]

---

[217]See S. Conf. Rep. No. 93-1200, at 13.

[218]120 Cong. Rec. 17033 (1974) (statement of Sen. Hart).

[219]See Pollard v. FBI, 705 F.2d 1151, 1155 (9th Cir. 1983).

[220]5 U.S.C. § 552(c)(2).

[221]See Rosenfeld v. United States Dep't of Justice, 57 F.3d 803, 814 (9th Cir. 1995).

[222]S. Conf. Rep. No. 93-1200, at 13.

[223]See also Voelker v. FBI, 638 F. Supp. 571, 573 (E. D. Mo. 1986).

[224]Landano, 508 U.S. at 179.

[225]See Hale v. United States Dep't of Justice, 99 F.3d 1025, 1031 (10th Cir. 1996).

The second clause of Exemption 7(D) protects all *information* furnished to law enforcement authorities by confidential sources in the course of national security intelligence investigations, which includes investigations conducted by federal agency inspectors general.[226] Exemption 7(D) protection has been extended to information supplied to federal officials by state or local enforcement authorities seeking assistance in pursuing nonfederal investigations. Under the second clause of Exemption 7(D), courts have permitted the withholding of confidential information even after the source's identity has been officially divulged or acknowledged, or when the requester knows the source's identity.[227]

In general, source-provided information remains protected even when some of it has been the subject of testimony in "open court."[228] Nor is the protection of Exemption 7(D) forfeited by court-ordered and court-supervised disclosure to an opponent in civil discovery.[229] However, if the "exact information given to the [law enforcement agency] has already become public, and the fact that the informant gave the same information to the [agency] is also public, there would be no grounds to withhold."[230] Under case law, Exemption 7(D)'s protection for sources and the information they have provided is in no way diminished by the fact that an investigation has been closed.[231] Additionally, unlike with Exemption 7(C), the safeguards of Exemption 7(D) remain undiminished by the death of the source.

EXEMPTION 7(E)

Exemption 7(E) affords protection to all law enforcement information which "would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably

---

[226]See Ortiz v. HHS, 70 F.3d 729, 732 (2d Cir. 1995), cert. denied, 116 S.Ct. 1422 (1996) [ruling that Exemption 7(D) properly applied when "HHS's Office of Inspector General...use[d anonymous] letter to launch a criminal investigation"].

[227]See, e.g., Jones v. FBI, 41 F.3d 238 (6th Cir. 1994) [explaining that Exemption 7(D) "focuses on the source's intent, not the world's knowledge"].

[228]Id. at 249.

[229]Donohue v. United States Dep't of Justice, No. 84-3451, 1987 U.S. Dist. LEXIS 15185, at *14 (D.D.C. Dec. 23, 1987).

[230]Dow Jones & Co. v. Department of Justice, 908 F.2d 1006 (D.C. Cir.) superseded, 917 F.2d 571, 577 (D.C. Cir. 1990).

[231]See Ortiz, 70 F.3d at 733 (ruling that "the status of the investigation is...immaterial to the application of the exemption").

be expected to risk circumvention of the law."[232]

The first clause of Exemption 7(E) (techniques and procedures) is designed to provide "categorical" protection of the information so described.[233] However, in order for the exemption to apply, the technique or procedure at issue must not be already well known to the public.[234] In some cases, however, commonly known procedures have been protected from disclosure when "the circumstances of their usefulness...may not be widely known."[235] Courts have justified withholding a wide variety of commonly known procedures on the basis that their disclosure could reduce or nullify their effectiveness.[236]

Exemption 7(E) authorizes the withholding of information consisting of, or reflecting, a law enforcement "technique" or a law enforcement "procedure," wherever it is used for "law enforcement investigations or prosecutions" generally. Law enforcement manuals meet the requirements for withholding under Exemption 7(E) to the extent that they consist of, or reflect, law enforcement techniques and procedures that are confidential.[237]

EXEMPTION 7(F)

Exemption 7(F) of the FOIA permits the withholding of information necessary to protect the physical safety of a wide range of individuals. Courts have held that the exemption affords protection of the names and identifying information of "...federal employees and third persons who may be unknown" to the requester in connection with particular law enforcement matters,[238] and of informants who have been threatened with harm.[239] Exemption 7(F)'s coverage is in a large part duplicative of that afforded by Exemption 7(C), except that it is potentially broader in that it requires no balancing of the individual's privacy interest vs. the public's interest in

---

[232]5 U.S.C. § 552(b)(7)(E).

[233]See, e.g., American Civil Liberties Union Found. v. United States Dep't of Justice, 833 F. Supp. 399, 407 (S.D.N.Y. 1993) (The first clause of Exemption 7(E) does not "necessarily require an individualized showing for each document.").

[234]See Campbell v. United States Dep't of Justice, No. 89-cv-3016, slip op. at 6 (D.D.C. Aug. 6, 1997) (declaring that Exemption 7(E) applies to "obscure or secret techniques").

[235]Wickline v. FBI, No. 92-1189, 1994 WL 549756, at *5 (D.D.C. Sept. 30, 1994) (quoting Parker v. United States Dep't of Justice, No. 88-0760, slip op. at 8 (D.D.C. Feb. 28, 1990), aff'd in pertinent part, No. 90-5070 (D.C. Cir. June 28, 1990)).

[236]See, e.g., Hale v. United States Dep't of Justice, 973 F.2d 894, 902-03 (10th Cir. 1992).

[237]Church of Scientology Int'l. v. IRS, 845 F. Supp. 714, 723 (C.D. Cal. 1993).

[238]Anderson v. United States Marshal Serv., 943 F. Supp. 37, 40 (D.D.C. 1996).

[239]Housley v. FBI, Nos. 87-2579, 87-3231, slip op. at 7 (D.D.C. March 18, 1988).

disclosure. Agencies can reasonably infer that Exemption 7(E) affords protection to information whenever there is a reasonable likelihood of its disclosure risking physical harm to someone.[240]

EXEMPTION 8

Exemption 8[241] of the FOIA protects matters that are "contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions."[242]

EXEMPTION 9

Exemption 9 of the FOIA covers "geological and geophysical information and data, including maps, concerning wells."[243] This exemption is rarely invoked or interpreted.

EXCLUSIONS

The FOIA has three special protection provisions, referred to as record "exclusions," to protect certain especially sensitive law enforcement matters.[244] These provisions allow federal government agencies to treat these types of records as "not subjected to the requirements of [the FOIA]."[245] An agency considering using an exclusion provision should first consult with the Department of Justice. Therefore, if an FDA component is interested in using an exclusion provision, please contact Betty Dorsey, Director, Freedom of Information Staff (HFI-35), and, if the office is in ORA, Shari Sheehan, Regulatory Counsel, Office of Enforcement, Division of Compliance Policy (HFC-230).

Using an "exclusion" is different from using the **"Glomarization"** concept. "Glomarization" refers to the situation in which an agency expressly *refuses to confirm or deny* the existence of records responsive to a request. Whereas, the application of one of the three record exclusions

---

[240]See FOIA Update, Summer/Fall 1993, at 4-5 (regarding Attorney General Janet Reno's "foreseeable harm" standard governing use of FOIA exemptions); see also FOIA Update, Spring 1994, at 3.

[241]FDA does not use Exemption 8.

[242]5 U.S.C. § 552(b)(8).

[243]5 U.S.C. § 552(b)(9).

[244]Id. § 552(c)(1), (c)(2), (c)(3); see also Attorney General's Memorandum on the 1986 Amendments to the Freedom of Information Act 18-30 (Dec. 1987).

[245]See Tanks v. Huff, No. 95-568, slip op. at 12 (D.D.C. May 24, 1996), appeal dismissed, No. 96-5180 (D.C. Cir. Aug. 13, 1996).

results in a response to the FOIA requester stating that *no records responsive to his FOIA request exist.*[246]

An agency that could employ at least one of the three exclusion provisions should ensure that its FOIA communications are consistently phrased so that a requester cannot ever discern the existence of any excluded records, or of any matter underlying them, through the agency's response to his FOIA request.

The (c)(1) Exclusion

The (c)(1) exclusion [5 U.S.C. § 552(c)(1)] provides as follows:

> Whenever a request is made which involves access to records described in subsection (b)(7)(A) and (A) the investigation or proceeding involves a possible violation of criminal law; and (B) there is reason to believe that (i) the subject of the investigation or proceeding is not aware of its pendency, and (ii) disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, the agency may, during only such time as that circumstance continues, treat the records as not subject to the requirements of this section.

The records in question must be those which would otherwise be withheld in their entireties under Exemption 7(A). Also, they must relate to an "investigation or proceeding [that] involves a possible violation of *criminal* law"[247] (emphasis added). An agency must consider whether it has "reason to believe" that the investigation's *subject is not aware* of its pendency, and that the agency's *disclosure of* the very *existence* of the records in question "could reasonably be *expected to interfere* with enforcement proceedings"[248] (emphasis added). Finally, the (c)(1) exclusion provision is *applicable "during only such time"* as the above-required circumstances exist.

The (c)(2) Exclusion

The "(c)(2) exclusion" [5 U.S.C. § 552(c)(2)] provides as follows:

> Whenever informant records maintained by a criminal law enforcement agency under an informant's name or personal identifier are requested by a third party according to the informant's name or personal identifier, the agency may treat the records as not subject to the requirements of [the FOIA] unless the informant's status as an informant has been officially confirmed.

---

[246]See also Steinberg v. United States Dep't of Justice, No. 93-2409, 1997 WL 349997, at *1 (D.D.C. June 18, 1997).

[247]5 U.S.C. § 552(c)(1)(A).

[248]Id. § 552(c)(1)(B).

As with Exemption 7(A), invoking Exemption 7(D) in response to a FOIA request tells the requester that somewhere within the records encompassed by his particular request there is reference to at least one confidential source. Under ordinary circumstances the disclosure of this fact poses no direct threat. Under extraordinary circumstances, this disclosure could result in devastating harms to the source and to the system of confidentiality existing between sources and criminal law enforcement agencies. An example would be if the ringleaders of a criminal enterprise suspect that they have been infiltrated by a source and they force all participants in the enterprise to either directly request that any law enforcement files on them be disclosed to the organization or to execute privacy waivers authorizing disclosure of their files in response to a request from the organization.

By its terms, the exclusion becomes inapplicable once the individual's status as a source has been *officially confirmed.*[249] The (c)(2) exclusion cannot be read to automatically require disclosure of source-related *information* once a *source* has been officially acknowledged, so long as the information may be properly protected under a FOIA exemption.[250]

It is important that all information which ordinarily would be disclosed to a first-party requester, other than information which would reflect that an individual is a confidential source, be disclosed. If, for example, the Federal Bureau of Investigation were to respond to a request for records pertaining to an individual having *a known record* of federal prosecutions by replying that "there exist no records responsive to your FOIA request," the interested criminal organization would recognize that its request had been afforded extraordinary treatment and would draw its conclusions accordingly.

The (c)(3) Exclusion

The "(c)(3)" exclusion [5 U.S.C. § 552(c)(3)] provides as follows:

> Whenever a request is made which involves access to records maintained by the Federal Bureau of Investigation pertaining to foreign intelligence or counterintelligence, or international terrorism, and the existence of the records is classified information as provided in [Exemption 1], the Bureau may, as long as the existence of the records remains classified information, treat the records as not subject to the requirements of [the FOIA].

This exclusion recognizes the exceptional sensitivity of the FBI's activities.

In conclusion, there are several important procedural issues to consider regarding the FOIA's

---

[249]Tanks, No. 95-568, slip op. at 12-13 (D.D.C. May 24, 1996).

[250]See Benavides v. DEA, 968 F.2d 1243, 1248 (D.C. Cir. 1992).

three exclusion provisions. The recipient of a "no records" response may challenge it because he believes that the agency has failed to conduct a sufficiently detailed search to uncover the requested records.[251] Alternately, any requester, mindful of the exclusion mechanism and seeking highly sensitive information of a nature which could possibly trigger an exclusion, could seek review of an agency response in an effort to pursue his suspicions and to have a court determine whether an exclusion, if in fact used, was appropriately employed. Agencies should prepare in advance a uniform procedure to handle administrative appeals and court challenges which seek review of the possibility that an exclusion was used. Finally, to preserve the effectiveness of the exclusion mechanism, requesters who inquire whether an exclusion has been used should routinely be advised that it is the agency's standard policy to refuse to confirm or deny that an exclusion was employed in any particular case.[252]

DISCRETIONARY DISCLOSURE AND WAIVER

The FOIA is an information disclosure statute with an emphasis on the "fullest responsible disclosure."[253] Agencies are free to make "discretionary disclosures" of exempt information, as a matter of sound policy, whenever they are not otherwise prohibited from doing so.[254] When agencies make discretionary disclosures of exempt information pursuant to Attorney General Janet Reno's FOIA Memorandum[255] describing the **"foreseeable harm standard"** they should not be held to have "waived" their ability to invoke applicable FOIA exemptions for similar or related information in the future. In other situations, however, various types of agency conduct and circumstances can reasonably be held to result in a FOIA exemption waiver.

Discretionary Disclosure

As a general rule, an agency's ability to make a discretionary disclosure of exempt information in accordance with Attorney General Janet Reno's 1993 FOIA Memorandum[256] will vary according to the nature of the FOIA exemption and the underlying interests involved. Agencies are obliged to not make a discretionary FOIA disclosure of the types of information covered by the following

---

[251]See Attorney General's Memorandum on the 1986 Memorandum to the Freedom of Information Act 27 (Dec. 1987); Oglesby v. United States Dep't of the Army, 920 F.2d 57, 67 (D.C. Cir. 1990).

[252]See FOIA Update, Spring 1991.

[253]S. Rep. No. 89-813, at 3 (1965); see FOIA Update, Summer 1988, at 14.

[254]See CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1334 n. 1 (D.C. Cir. 1987).

[255]See FOIA Update, Spring 1997.

[256]See FOIA Update, Spring 1997, at 1 (describing Attorney General's reiteration of the importance of "foreseeable harm" standard to federal agencies in order to promote further discretionary disclosure in agency decisionmaking).

FOIA exemptions:

Exemption 1 (classified information concerning the national defense or foreign policy). If information is properly classified and therefore is exempt from disclosure under Exemption 1, it is not appropriate for discretionary FOIA disclosure.[257]

Exemption 3 (accommodates the nondisclosure provisions that are contained in a variety of other federal statutes). Agencies ordinarily do not make discretionary disclosure under the FOIA of information that falls within the scope of Exemption 3.[258]

Exemption 4 (trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential). The Trade Secrets Act[259] prohibits the unauthorized disclosure of most (if not all) of the information falling within Exemption 4. In effect, the Trade Secrets Act prohibits an agency from making a discretionary disclosure of Exemption 4 information absent an agency regulation that expressly authorizes disclosure.[260]

Exemptions 6 and 7(C) (personal privacy information). The personal information protected by Exemptions 6 and 7(C) is not the type of information ordinarily considered appropriate for discretionary FOIA disclosure; with these exemptions, a balancing of public interest considerations is built into the determination of whether the information is exempt in the first place. Also, the Privacy Act of 1974[261] mandates that personal privacy information concerning U.S. citizens and permanent-resident aliens that is maintained in a "system of records"[262] not be disclosed unless that disclosure is permitted under one of the specific exceptions to the Privacy Act's general disclosure prohibition. One of the exceptions in the Privacy Act relates to the FOIA, however, the Privacy Act permits only those disclosures that are "required" by the FOIA, so discretionary FOIA disclosures of personal privacy information are incompatible with the Privacy Act.

Examples of information that generally are appropriate for discretionary disclosure under the FOIA are information covered by the FOIA:

Exemption "low 2" (administrative information of a trivial nature). Nearly all "low 2"

---

[257]See generally FOIA Update, Winter 1985, at 1-2.

[258]See FOIA Update, Fall 1994, at 7.

[259]See 18 U.S.C. § 1905 (1994); see FOIA Update, Summer 1985, at 3.

[260]Chrysler Corp. v. Brown, 441 U.S. at 295-96 (1979).

[261]5 U.S.C. § 552(a).

[262]Id. § 552(a)(5).

information should be appropriate for discretionary disclosure under the "**foreseeable harm**" standard established by Attorney General Janet Reno.

Exemption 5 (deliberative process, and attorney work-product and attorney-client privileges). The most common examples of information appropriate for discretional FOIA disclosure can be found under Exemption 5, after a consideration of a number of factors, including the circumstances of the decisionmaking process involved.

Exemption 7(D) (as it relates to *information* provided by a confidential source). The Department of Justice changed its policy[263] so as to encourage discretionary disclosure of the information furnished by confidential sources in criminal investigations whenever that is possible without foreseeable source identification and harm.

Exemption 7(E) (techniques and procedures for law enforcement investigations; guidelines). Exemption 7(E) affords very broad coverage of "law enforcement techniques" and, therefore, holds much potential for discretionary disclosure.

Exemption 8 (reports of financial institutions).

As Attorney General Janet Reno's October 1993 Memorandum points out, making a discretionary disclosure under the FOIA can significantly lessen an agency's burden at all levels of the administrative process, and it also eliminates the possibility that the information in question will become the subject of litigation, thereby conserving scarce agency resources.[264] Courts generally have found that the release of certain documents as a result of discretionary disclosure, waives FOIA exemptions only for those documents released.[265]

Waiver

Sometimes, when a FOIA exemption is being invoked, a further inquiry must be undertaken: a determination of whether, through some prior disclosure or an express authorization, the applicability of the exemption has been waived. First, if the prior disclosure does not "match" the exempt information in question, the difference between the two might itself be a sufficient basis for reaching the conclusion that no waiver has occurred.[266] However, courts do look harshly upon prior disclosures that result in unfairness.[267] An agency's failure to heed its own

---

[263]See FOIA Updates, Summer/Fall 1993, at 10, and Fall 1994, at 7.

[264]See FOIA Update, Fall 1994, at 7.

[265]See Mobil Oil Corp. v. EPA, 879 F.2d at 701.

[266]See, e.g., Public Citizen v. Department of State, 11 F.3d 198, 201 (D.C. Cir. 1993).

[267]See, e.g., North Dakota ex rel. Olson v. Department of Interior, 581 F.2d 177, 182 (8th Cir. 1978). ("selective disclosure" of record to one party in litigation deemed "offensive" to FOIA

regulations regarding circulation of internal agency documents was found determinative and led to a finding of waiver.[268] Similarly, an agency's personnel regulation requiring disclosure of (or a promise by an agency official to disclose) the information, an agency's carelessness in permitting access to certain information, and an agency's mistaken disclosure of the contents of a document have all resulted in waiver.[269]

On the other hand, waiver is not necessarily found when an agency makes an entirely mistaken disclosure.[270] An oral disclosure may be treated as not so different from a written one, risking a waiver result. An agency's failure to treat information in a responsible, appropriate fashion should not result in a waiver, if the failure was due to a "leak" of information, which is an unauthorized disclosure.[271] However, "official" disclosures, i.e., direct acknowledgments by authoritative government officials, may well waive an otherwise applicable FOIA exemption.[272]

FEES

The FOIA provides for three levels of fees that may be assessed in response to FOIA requests according to categories of FOIA requesters, with limitations of fees to be charged depending on the identity of the requester and the intended use of the requested information.[273] [As to fees that FDA assesses, see ORA's publications, "Regulatory Procedures Manual," (August 1997), chapter 8, subchapter "Freedom of Information Act (FOIA)," (general information) and "ORA EFOIA Guidance #2," (March 1998) (sample chart to use when determining fees)].

---

and held to prevent agency's subsequent invocation of Exemption 5 against the other party to litigation).

[268]Shermco Indus. v. Secretary of the Air Force, 613 F.2d 1314, 1320 (5th Cir. 1980).

[269]See also Gannett River States Publ'g Corp. v. Bureau of the Nat'l Guard, No. J91-0455-L, slip op. at 14 (S.D. Miss. Mar. 2, 1992) (privacy interests in withholding identities of soldiers disciplined for causing accident is de minimis because agency previously released much identifying information).

[270]Public Citizen Health Research Group v. FDA, 953 F. Supp. 400, 404-06 (D.D.C. 1996) (holding no waiver where material accidently released and information not disseminated by requester).

[271]See, e.g., Simmons v. United States Dep't of Justice, 796 F.2d 709, 712 (4th Cir. 1986) (unauthorized disclosure does not constitute waiver).

[272]See Abbotts v. NRC, 766 F.2d 604, 607-08 (D.C. Cir. 1985).

[273]See FOIA Update, Winter/Spring 1987, at 2; OMB Fee Guidelines, 52 Fed. Reg. 10,011 (1987).

The FDA's FOI Staff (HFI-35) determines the appropriate category of requester. The categories are: (1) commercial use, (2) educational or noncommercial scientific institution, and (3) requesters who do not fall within the prior two categories.

The first level of fees includes charges for document *search, duplication and review*, when records are requested for commercial use. "Search" costs include all the time spent looking for responsive material, including page-by-page or line-by-line identification of material in documents. Agencies may charge for search time even if they fail to locate any records responsive to the request or if the records located are subsequently determined to be exempt from disclosure. As now defined by the EFOIA[274] the term "search" means locating records or information either "manually or by automated means" and can require agencies to expend "reasonable efforts" in electronic searches, if requested to do so by requesters willing to pay for that search activity.[275] "Review" costs which may be charged to commercial-use requesters include costs for the time to process or prepare the documents for disclosure, but it does not include time spent resolving general legal or policy issues regarding applicability of exemptions or reviewing on appeal exemptions already applied. "Duplication" charges represent the reasonable "direct costs" of making copies (paper, microforms, or machine-readable) of documents. For copies prepared by computer, such as printouts, agencies should charge the actual costs of product of the printout.

The second level of fees limits charges to document *duplication costs only*, "when the records are not sought for commercial use and the request is made by an educational or noncommercial scientific institution, whose purpose is scholarly or scientific research; or a representative[276] of the news media."

The third level of fees, which applies to all requesters who do not fall within either of the preceding two fee levels, consists of reasonable charges for document *search and duplication.*

All categories of requesters may be charged the actual "direct costs" involved when an agency complies with a request for "special services," such as certifying records as true copies or mailing records by express mail, or, as long as the agency does not relinquish responsibilities it alone must perform, using a contractor. No FOIA fee may be charged by an agency if the government's cost of collecting and processing the fee is likely to equal or exceed the amount of the fee itself. In addition, except for commercial-use requesters, agencies must provide the first 100 pages of duplication, as well as the first two hours of search time, without cost to the requester. Agencies should not begin to assess fees until after they provide this amount of free search and duplication; the assessable fee for any requester then must be greater than the agency's cost to collect and process it in order for the fee to actually be charged.

---

[274]Pub. L. No. 104-231, 110 Stat. 3048.

[275]5 U.S.C. § 552(a)(3)(C); see also FOIA Update, Winter 1997, at 6.

[276]Id. § 552(a)(4)(A)(ii)(II).

Agencies may not require a requester to make an advance payment, i.e., payment before work is begun or continued, unless the agency first estimates that the assessable fee is likely to exceed $250, or unless the requester has previously failed to pay a properly assessed fee in a timely manner (i.e., within thirty days of the billing date).[277] Requesters have been found not to have exhausted their administrative remedies when fee requirements have not been met. The FOIA contains no provision for reimbursement of fees when the requester is dissatisfied with the agency's response.

FEE WAIVERS

The FOIA's fee waiver standard contains two basic requirements--the public interest requirement and the requirement that the requester's commercial interest in the disclosure, if any, must be less than the public interest in it.[278] To determine whether the *first* fee waiver requirement has been met, agencies should consider the following four factors in sequence:

1. The subject matter of the requested records, in the context of the request, must specifically concern identifiable "operations or activities of the government."[279]

2. The disclosable portions of the requested information must be meaningfully informative in relation to the subject matter of the request.[280]

3. The disclosure must contribute to the understanding of the public at large, as opposed to the individual understanding of the requester or a narrow segment of interested persons.[281] Agencies should evaluate the identity and qualifications of the requester--e.g., expertise in the subject area of the request and ability and intention to disseminate the information to the public--in order to determine whether the public would benefit from disclosure to

---

[277]See id. § 552(a)(4)(A)(v); see also OMB Fee Guidelines, 52 Fed. Reg. 10,011, 10,020 (1987).

[278]See id. § 552(a)(4)(A) (iii), as amended by Electronic Freedom of Information Act Amendments of 1996; see also 28 C.F.R. § 16.10(d) (1996); Revised Department of Justice Freedom of Information Act Regulations, 62 Fed. Reg. 45,184, 45,191 (1997) (to be codified at 28 C.F.R. pt. 16) (proposed Aug. 26, 1997); see also, ORA's publication, "Regulatory Procedures Manual," Chapter 8, subchapter, "Freedom of Information Act (FOIA)," (August 1997).

[279]See Dollinger v. United States Postal Serv., No. 95-CV-6174T, slip op. at 4 (W.D.N.Y. Aug. 24, 1995).

[280]See FOIA Update, Winter/Spring 1987, at 6.

[281]Carney v. United States Dep't of Justice, 19 F.3d 807, 814 (2d Cir. 1994).

that requester.[282]

4. The public's understanding of the subject matter in question, as compared to the level of public understanding existing prior to the disclosure, must be likely to be enhanced by the disclosure to a significant extent.[283]

Once an agency determines that the "public interest" requirement for a fee waiver has been met, it should focus on the standard's *second* requirement and consider the following two factors in sequence to determine whether the disclosure of the information is not in the commercial interest of the requester:

1. Determine whether the request involves any commercial interest of the requester which would be furthered by the disclosure. A "commercial interest" is one that furthers a commercial, trade, or profit interest as those terms are commonly understood.[284]

2. Balance the requester's commercial interest against the identified public interest in disclosure and determine which interest is "primary."

A fee waiver or reduction must be granted when the public interest in disclosure is greater in magnitude than the requester's commercial interest. When agencies analyze fee waiver requests by considering these six factors, they can rest assured that they have carried out their statutory obligation to determine whether a waiver is in the public interest.[285]

Litigation Considerations

"Freedom of Information Act cases are peculiarly difficult."[286] Under Attorney General Janet Reno's October 4, 1993, memorandum (**"foreseeable harm"**), she ordered a review of all pending and future FOIA litigation, which has led to the disclosure of additional information in many instances and to the complete resolution of several FOIA lawsuits.[287]

United States District Courts are vested with exclusive jurisdiction over FOIA cases by section

---

[282]McClain v. United States Dep't of Justice, 13 F.3d 220, 221 (7th Cir. 1993).

[283]See Sierra Club Legal Defense Fund v. Bibles, No. C92-1413 (W.D. Wash. Feb. 17, 1993), aff'd No. 93-35383 (9th Cir. Aug. 29, 1994) (unpublished memorandum), 34 F.3d 1073 (9th Cir. 1994).

[284]See FOIA Update, Winter/Spring 1987, at 9.

[285]See FOIA Update, Winter/Spring 1987, at 10.

[286]Miscavige v. IRS, 2 F.3d 366, 367 (11th Cir. 1993).

[287]See FOIA Updates, Fall 1994, at 7, and Spring 1994, at 1.

(a)(4)(B) of the Act[288]. That provision's language limits relief under the FOIA to disclosure of records to a particular requester; it does not authorize a court to order publication of information, even information required to be published under subsection (a)(1) of the FOIA,[289] or to order that agency records be made available for public inspection in an agency reading room.

Courts have held that the determination of whether an agency has improperly withheld records usually turns on the application of one or more exemptions applied to the documents at issue. If an agency can establish that no responsive records exist, or that all responsive records have been released to the requester, the agency's refusal to produce them should not be deemed an improper withholding.[290] An agency has not improperly withheld records when it is prohibited from disclosing them by a preexisting court order.[291]

A FOIA plaintiff, i.e., a requester who sues an agency, must file suit before expiration of the applicable statute of limitations. A court has held that the FOIA cause of action accrued--and, therefore, the statute of limitations began to run--once the plaintiff had "constructively" exhausted his administrative remedies and not when all administrative appeals had been finally adjudicated.[292]

Note that FDA's regulations[293] provide the following retention schedule: (1) files created by the receipt of and response to FOIA requests, except denials and/or appeals, may be destroyed 2 years from date of final response, (2) files created by a FOIA request which was wholly or partially denied may be destroyed 5 years after the denial letter was issued, and (3) files created by a FOIA request which was wholly or partially denied and which denial was subsequently appealed to the DHHS may be destroyed 4 years after final determination by FDA or 3 years after final adjudication by courts, whichever is later.

The general rule under the FOIA is that a requester must exhaust administrative remedies prior to

---

[288]5 U.S.C. § 552(a)(4)(B).

[289]See Kennecott Utah Copper Corp. v. United States Dep't of the Interior, 88 F.3d 1191, 1202 (D.C. Cir. 1996).

[290]See D'Angelica v. IRS, No. CIV. S-94-1998, 1996 U.S. Dist. LEXIS 6681, at *3 (E.D. Cal. Apr. 25, 1996).

[291]See FOIA Update, Summer 1983, at 5. But see, FOIA Update, Summer 1992, at 5 (advising that "protective orders" issued by administrative law judges do not qualify as such court orders).

[292]Spannaus v. Department of Justice, 824 F.2d 52, 57-59 (D.C. Cir. 1987). (D.C. Circuit applied the general federal statute of limitations, 28 U.S.C. § 2401(a), to FOIA actions).

[293]21 C.F.R. § 20.31 (a)(1) through (a)(3).

judicial review.[294] The FOIA permits requesters to treat an agency's failure to comply with its specific time limits as full, or "constructive," exhaustion of administrative remedies. This special right of judicial review ends, however, if an agency responds to a request at any time before the requester files the lawsuit. In that case, the requester must administratively appeal a denial and wait at least twenty working days for the agency to adjudicate that appeal before commencing litigation.[295] Regardless of whether the agency's response is timely, the requester's exhaustion obligation may be excused if the agency's response fails to supply notice of the right to file an administrative appeal, as required by 5 U.S.C. § (a)(6)(A)(i).

An agency response that merely acknowledges receipt of a request does not constitute a "determination" under the FOIA in that it neither denies records nor grants the right to appeal the agency's determination.[296] Regardless of whether the agency has met its appropriate time limits for processing responses or appeals, requesters have been deemed not to have constructively exhausted administrative remedies when they have failed to comply with necessary requirements of the FOIA's administrative process. Courts have held the following as examples of requesters' failures to comply, when they have failed to: (1) provide required proof of identity in first-party requests or authorization by third parties, (2) "reasonably describe" the records sought, (3) comply with fee requirements, (4) pay authorized fees incurred in a prior request before making new requests, (5) present for review at the administrative appeal level any objection to earlier processing practices, or (6) administratively request a waiver of fees or to challenge a fee waiver denial at the administrative appeal level.

"Open America" Stays of Proceedings

Even when a requester has constructively exhausted administrative remedies, due to an agency's failure to comply with the FOIA's time deadlines, the Act provides that the court may allow the agency additional time to complete its processing of a request, if it can be shown that "exceptional circumstances exist and that the agency is exercising due diligence in responding to the request."[297] The Court of Appeals for the District of Columbia Circuit held that "exceptional circumstances" may exist when an agency can show that it "is deluged with a volume of requests for information vastly in excess of that anticipated by Congress [and] when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection

---

[294]See, e.g., Pollack v. Department of Justice, 49 F.3d 115, 118 (4th Cir. 1995).

[295]See Oglesby v. United States Department of the Army, 920 F.2d at 57; see also, 5 U.S.C. § 552(a)(6)(A)(ii).

[296]See Martinez v. FBI, 3 Gov't Disclosure Serv. (P-H) ¶ 83,005, at 83,435 (D.D.C. Dec. 1, 1982); FOIA Update, Summer 1992; "Regulatory Procedures Manual," (August 1997), Chapter 8, subchapter, "Freedom of Information Act (FOIA)."

[297]5 U.S.C. § 552(a)(6)(C) (1994), as amended by Electronic Freedom of Information Act Amendments of 1996.

(6)(A)."[298] Note, however, that the Electronic FOIA Amendments may have a very significant impact on the ability of some agencies to obtain Open America stays in the future. Although the Electronic FOIA amendments do not legislatively overturn the Open America decision, they do substantially limit it by providing that "the term 'exceptional circumstances' does not include a delay that results from a predictable agency workload of requests...unless the agency demonstrates reasonable progress in reducing its backlog of pending requests."[299]

The Electronic FOIA amendments will also have an effect on the criteria and procedures governing requests for expedited processing. Agencies are now required to promulgate regulations providing for the granting of expedited treatment in cases of "compelling need" or "in other cases determined by the agency."[300] The term "compelling need" now codifies the traditional understanding that expedited treatment will be granted: (A) whenever the withholding of the requested records "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual,"[301] or (B) "with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."[302] Absent truly exceptional circumstances, courts have generally declined to order expedited processing when records are "needed" for post-judgment attacks on criminal convictions, or for use in other civil litigation. Courts have held that publishing deadlines are not sufficient grounds for expediting processing.[303]

Adequacy of Search

To prevail in a FOIA action, the agency must prove that "each document that falls within the class requested either has been produced, is identifiable, or is wholly exempt from the Act's inspection requirements."[304] Therefore, an agency is under a duty to conduct a "reasonable search" for responsive records.[305]

---

[298]See Open America v. Watergate Special Prosecution Force, 547 F.2d 605 (D.C. Cir. 1976).

[299]5 U.S.C. § 552(a)(6)(C)(ii); see FOIA Updates, Fall 1996, at 10, and Summer 1997, at 3-7.

[300]Id. § 552(a)(6)(E)(i); see FOIA Update, Fall 1996, at 10.

[301]Id. § 552(a)(6)(E)(v)(I).

[302]Id. § 552(a)(6)(E)(v)(II); see also Revised Department of Justice FOIA Regulations, 62 Fed. Reg. at 45,187 (1997).

[303]See, e.g., Freeman v. United States Dep't of Justice, 822 F. Supp. 1064, 1067 (S.D.N.Y. 1993).

[304]Miller v. United States Dep't of State, 779 F.2d 1378, 1383 (8th Cir. 1985) (citing National Cable Television Ass'n v. FCC, 479 F.2d 183, 186 (D.C. Cir. 1973).

[305]See, e.g., Patterson v. IRS, 56 F.3d 832, 841 (7th Cir. 1995).

The adequacy of a search is "dependent upon the circumstances of the case."[306] Courts have determined that an agency must show that it made a good faith effort to find the records requested. The question is not "whether there might exist any other documents possibly responsive to the request, but rather whether the search for those documents was adequate."[307]

Although an agency's search may be found insufficient if the court concludes that it interpreted the scope of the request too narrowly,[308] the Court of Appeals for the District of Columbia Circuit has expressly held that an agency "is not obligated to look beyond the four corners of the request for leads to the location of responsive documents."[309] In extraordinarily onerous cases, an agency may not be compelled to undertake a requested search that is of such enormous magnitude as to make it "unreasonably burdensome."[310] It has frequently been held that agencies that maintain field offices in various locations are not ordinarily obligated to search offices other than those to which the request has been directed.[311]

"Vaughn Index"

In FOIA litigation, the defendant agency bears the burden of sustaining its action of withholding records. The most commonly used device for meeting this burden of proof is the "Vaughn Index," fashioned by the Court of Appeals for the District of Columbia Circuit more than two decades ago in a case entitled Vaughn v. Rosen.[312] The Vaughn decision required agencies to prepare an itemized index, correlating each withheld document (or portion) with a specific FOIA exemption and the relevant part of the agency's nondisclosure justification.[313] This index not only makes the trial court's job more manageable, it also enhances appellate review by ensuring that a full public record is available upon which to base an appellate decision.

---

[306]Truitt v. Department of State, 897 F.2d 540, 542 (D.C. Cir. 1990).

[307]Steinberg v. United States Dep't of Justice, 23 F.3d 548, 551 (D.C. Cir. 1994) (quoting Weisberg v. United States Dep't of Justice, 745 F.2d at 1485.

[308]Nation Magazine v. United States Customs Serv., 71 F.3d 885, 889-91 (D.C. Cir. 1995).

[309]Kowalczyk v. Department of Justice, 73 F.3d 386, 389 (D.C. Cir. 1996).

[310]Nation Magazine, 71 F.3d at 891-92 (rejecting demand that agency search "through 23 years of unindexed files for records pertaining" to subject while remanding for focus on narrower search for dated memorandum in files indexed chronologically).

[311]See, e.g., Kowalczyk, 73 F.3d at 389 (When "the requester clearly states that he wants all agency records...regardless of their location, but fails to direct the agency's attention to any particular office than the one receiving the request, then the agency need pursue only a lead...that is both clear and certain.")

[312]484 F.2d 820 (D.C. Cir. 1973).

[313]Vaughn, 484 F.2d at 827.

Summary Judgment

Summary judgment is the procedural vehicle by which nearly all FOIA cases are resolved.[314] Motions for Summary Judgment are governed by Rule 56 of the Federal Rules of Civil Procedure, which provides, in part, that the "judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits,[315] if any, show that there is no genuine issue as to any material fact."[316] An agency's failure to respond to a FOIA request in a timely manner does not, by itself, justify an award of summary judgment to the requester.[317]

Discovery

Discovery is greatly restricted in FOIA actions. It is generally limited to the scope of an agency's search,[318] its indexing and classification procedures, and similar factual matters.[319]

"Reverse" FOIA

A "reverse" FOIA action is one in which the "submitter of information--usually a corporation or other business entity" that has supplied an agency with "data on its policies, operations or products--seeks to prevent the agency that collected the information from revealing it to a third party in response to the latter's FOIA request."[320] Typically, the submitter contends that the requested information falls within Exemption 4 of the FOIA.[321] In a reverse FOIA suit "the party seeking to prevent a disclosure the government itself is otherwise willing to make" assumes the

---

[314]See Cappabianca v. Commissioner, United States Customs Serv., 847 F. Supp. 1558, 1561 (M.D. Fla. 1994).

[315]An affidavit is a document signed by an agency official who is knowledgeable about the way in which information is processed. An example of an affidavit submitted by an agency in FOIA litigation would be one that identifies the documents at issue and explains why they fall under the claimed exemptions.

[316]Fed. R. Civ. P. 56(c).

[317]See Barvick v. Cisneros, 941 F. Supp. 1015, 1019-20 (D. Kan. 1996).

[318]See Ruotolo v. Department of Justice, 53 F.3d 4, 11 (2d Cir. 1995).

[319]See Katzman v. Freeh, 926 F. Supp. 316, 319-20 (E.D.N.Y. 1996).

[320]CNA Fin. Corp. v. Donovan, 830 F.2d at 1133 n. 1.

[321]5 U.S.C. § 552(b)(4).

burden of justifying nondisclosure.[322] A challenge to an agency's disclosure decision is reviewed in light of the "basic policy" of the FOIA to "open agency action to the light of public scrutiny."[323]

Because judicial review in reverse FOIA cases is ordinarily based on review of an agency's administrative record, it is vitally important that agencies take care to develop a comprehensive one.[324] Administrative practice in potential reverse FOIA situations is generally governed by an executive order issued a decade ago. Executive Order 12,600 requires federal agencies to establish certain predisclosure notification procedures which will assist agencies in developing adequate administrative records.[325] The executive order recognizes that submitters of proprietary information have certain procedural rights and it therefore mandates that notice be given to submitters of confidential commercial information whenever the agency "determines that it may be required to disclose" the requested data.[326] Questions related to predisclosure notification should be directed to the Director, FOI Staff (HFI-35), or Shari Sheehan, ORA (HFC-230).[327]

---

[322]Martin Marietta Corp. v. Dalton, No. 94-2702, 1997 WL 459831, at *5 n. 4. (D.D.C. August 8, 1997)

[323]Id. at *4.

[324]Reliance Elec. Co. v. Consumer Prod. Safety Comm'n, 924 F.2d 274, 277 (D.C. Cir. 1991) insisting that court "cannot properly perform" its reviewing function "unless the agency has explained the reasons for its decision").

[325]3 C.F.R. § 235 (1988), reprinted in 5 U.S.C. § 552 note (1994), and in FOIA Update, Summer 1987, at 2-3.

[326]Exec. Order No. 12,600, § 1.

[327]See also ORA's "Regulatory Procedures Manual" (August 1997), Chapter 8, subchapter, "Freedom of Information Act (FOIA)," p. 352-353 (describing FDA's predisclosure notification procedure).

SECTION II

Preambles to FDA Public Information Regulations

Section II

Preambles to FDA Public Information Regulations

In this section

This section contains preambles to FDA's 1974 and 1977 Public Information regulations.

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC INFORMATION

The Commissioner of Food and Drugs issued a notice of proposed rulemaking, published in the FEDERAL REGISTER of May 5, 1972 (37 FR 9128), on the disclosure of information to the public in conformity with Public Law 89-487, revised by Public Law 90-23, the public information section of the Administrative Procedures Act, known commonly as the "Freedom of Information Act."

The Commissioner received a total of 667 letters, 68 of which made substantive comments on one or more sections of the proposal. These letters were from individuals, consumer groups, nonprofit institutions and associations, trade associations, and representatives of companies subject to regulation under the laws administered by the Food and Drug Administration.

The bulk of the comments, mainly from individuals, made general observations in favor of the release of more or all information in government files to all who want to review it.

A small number of comments opposed in general any liberalization of disclosure policies on the ground that this posed a threat to free enterprise.

Most of the letters making substantive comments were concerned with various specific provisions of the regulations and contained recommendations for changes. These comments and recommendations and the Commissioner's conclusions concerning them are set out below.

The proposed regulations have been implemented since they were published except in a few minor respects. The Commissioner concluded not to issue final regulations immediately after the time for public comment on the proposal had expired, in order to gain experience under the proposal and because of pending litigation on the scope of the trade secrets exemption. Substantial experience has now been gained under the proposal, and the preamble and final regulations cover all of the types of issues that have arisen in the intervening 2 years. The pending litigation, "Morgan v. FDA," 495 F.2d 1075 (D.C. Cir. 1974), has been concluded. Accordingly, the Commissioner concludes that it is appropriate to issue these final regulations governing the handling of all public information requests by the Food and Drug Administration.

GENERAL POLICY AND ORGANIZATION OF THE FINAL REGULATIONS

1. When the proposed regulations were first published in May 1972, they represented a major change from prior agency policy. Whereas the agency formerly retained roughly 90 percent of the records in its files as confidential and disclosed only 10 percent, during the past 2 years it has reversed this proportion and now makes available roughly 90 percent of the records in its files. The Commissioner has carefully reviewed the impact of this policy on the Food and Drug Administration during the past 2 years, and concludes that it has had a beneficial rather than a detrimental effect. Contrary to fears expressed in many comments at the time the proposal was

published, this new policy of open disclosure has not hindered communications or relations with anyone outside the Federal government nor has it impeded internal agency deliberations. It has, of course, properly encouraged closer public scrutiny of Food and Drug Administration actions, and thus has fostered greater public accountability of the agency.

Accordingly, the Commissioner concludes not only that the open disclosure policy under the proposed regulations should be continued, but indeed that greater use should be made in the future of the Commissioner's discretionary authority to release agency records which, under the strict terms of the statute, could be retained as confidential. This policy is reflected in these final regulations. The Commissioner believes that this policy is in the best interests of both the public and the government.

2. The proposed regulations were divided into two different types of provisions. The general provisions relating to procedure, fees, exemptions, and some specific categories of agency records were included in Part 4 of Title 21 of the Code of Federal Regulations. Specific provisions relating to documents that are already the subject of regulations in other parts of Title 21 of the Code of Federal Regulations were incorporated directly into those other parts, such as the provisions relating to section 305 hearing records, food additive petitions, and new drug applications.

Upon review of the comments submitted on the proposal, the Commissioner concludes that this basic structure should be retained. Whenever possible, provisions relating to disclosure or nondisclosure of records should be incorporated into existing or new regulations dealing specifically with those types of documents.

The Commissioner has also concluded that the more general provisions in Part 4 require reorganization in order to group together the provisions that more closely relate to each other and to make these regulations more readable and understandable. Accordingly, Part 4 has been divided into six subparts, dealing with official testimony and information, general policy, procedures and fees, exemptions, limitations on exemptions, and the availability of specific types of documents of which requests are frequently made.

FREEDOM OF INFORMATION ACT AMENDMENTS

3. In October 1974 Congress passed H.R. 12471, the Freedom of Information Act amendments, to revise and add to a number of the existing provisions of the Freedom of Information Act. On October 17, 1974, the President vetoed this bill. On November 20 and 21, 1974, Congress voted to override the President's veto. The new amendments become effective 90 days after enactment, i.e., on February 19, 1975.

The Commissioner notes that, the concerns expressed by the President in his veto message are not applicable to the types of records contained in Food and Drug Administration files. Many of the provisions in the amendments reflect recommendations made earlier by the Administrative Conference of the United States or are already reflected in existing case law, in the regulations of the Department of Health, Education, and Welfare, and in the proposed Food and Drug

Administration regulations published in May 1972. Accordingly, the Food and Drug Administration has closely followed the legislative progress of these amendments in preparing these final regulations, so that the regulations would fully implement the new amendments. The Commissioner has carefully considered the final regulations published in this order, in the light of the congressional policy established in the amendments, and concludes that they meet both the spirit and the letter of the amended law.

GENERAL COMMENTS

4. Comments contended that the open disclosure policy set out in the proposed regulations published in May 1972 would increase product liability and other litigation problems for companies.

The Commissioner advises that the question of whether this type of litigation would increase or decrease is not a factor to be considered in determining the disclosure of information to the public under the Freedom of Information Act.

5. Comments contended that many Food and Drug Administration records and documents should not be disclosed because they could be distorted, misconstrued, and quoted out of context.

The Commissioner realizes that all public information can be abused. This is, however, not a reason for declining to comply with the requirements of the Freedom of Information Act.

6. One comment stated that, in the scientific world, the ability to publish an article containing data that have not previously been made available is a definite advantage. It was contended that those who create the data have a right to publish them without the threat of a prior disclosure of such data by the Food and Drug Administration.

The Commissioner concludes that, once disclosable data have been submitted to the Food and Drug Administration, they will be disclosed to the public upon request. Before any voluntary submission of unpublished scientific information to the Food and Drug Administration, the person submitting it will have an opportunity to obtain an opinion from the agency under the procedure established in § 4.44 of the regulations as to whether it will be disclosed to the public upon request, or whether it falls within an exemption from disclosure and thus will not be available for public disclosure.

The Freedom of Information Act contains no exemption permitting the Food and Drug Administration to withhold data from public disclosure solely on the ground that it is not yet published. Accordingly, unless data fall within one of the specific statutory exemptions from disclosure, the only positive means for a scientist to protect his first publication rights is to publish the information before submitting it to the Food and Drug Administration.

7. A comment contended that some data and information submitted to the Food and Drug Administration may not properly be copied for distribution to the public because of the copyright rights to it.

The Commissioner concludes that, to the extent that the Freedom of Information Act and the copyright laws conflict, the specific requirements for public disclosure under the Freedom of Information Act must be construed to prevail.

8. It was asserted in comments that there is no legal support for the provision contained in several places in the proposed regulations that records shall be disclosed unless "extraordinary circumstances" exist. It was suggested that guidelines be adopted to establish the meaning of "extraordinary circumstances."

The Commissioner advises that this type of provision creates a strong presumption of disclosure and requires any person who believes that a specific record falling within the rule should not be disclosed bears the burden of overcoming that presumption by showing unusual circumstances that justify nondisclosure. Because it is impossible to predict what facts would be sufficient to satisfy this burden, the Commissioner concludes that general guidelines are not feasible and that this type of provision will be administered on the basis of the facts shown in each case.

9. Several provisions in the proposed regulations published in May 1972 would have imposed the requirement that, within 180 days from the final regulations, any person who had previously submitted data or information to the Food and Drug Administration must review that material and, if confidentiality was desired and justified, submit a request that it be retained in confidence. Numerous comments objected to this provision on the grounds that it imposed an impossible burden on industry in light of the voluminous information submitted and that much of this information would never be requested anyway. It was almost uniformly suggested that this matter be handled on an ad hoc basis when requests for disclosure are received.

The Commissioner agrees with these comments, and has deleted all requirements for justifying the confidentiality of previously submitted material. When a request for information is received, and it clearly falls within the disclosure rules laid out in these final regulations, it will be disclosed at once. If the matter presents a close question, the affected person may be consulted pursuant to § 4.45. The Commissioner concludes that this procedure is sufficient and will reduce the burden on both the agency and persons who submit information.

10. Comments suggested that the decision of the Assistant General Counsel, Food and Drug Division, on disclosure should constitute final agency action since the Assistant Commissioner for Public Affairs did not appear to have the necessary legal expertise. A comment also suggested that the power to make final decisions on disclosure be placed in the office of the Associate Commissioner for Compliance who would then delegate this power to an Administrative Law Judge operating out of that office.

The Commissioner advises that it is in accordance with the policy of the Department of Health, Education, and Welfare to vest the power to make final decisions on public disclosure of records in the Assistant Commissioner for Public Affairs. The legal expertise of the Assistant General Counsel and the experience of the Associate Commissioner for Compliance is available to the Assistant Commissioner for Public Affairs at all times.

11. One comment stated that the proposed regulations of the Food and Drug Administration appear to go beyond the proposed regulations of the Department of Health, Education, and Welfare, and contended that the Food and Drug Administration has no authority to promulgate regulations different from the Department regulations.

The Department published its final regulations in the FEDERAL REGISTER of August 17, 1973 (38 FR 22231). Section 5.11 of those regulations (45 CFR 5.11) expressly recognizes that the Food and Drug Administration may issue its own supplementary regulations as long as they are consistent with the Department regulations. The Commissioner concludes that these final regulations are entirely consistent with the Department regulations.

12. Questions have arisen about the availability for public disclosure of the various types of petitions filed with the agency pursuant to the Administrative Procedure Act rather than pursuant to particular provisions of the Federal Food, Drug, and Cosmetic Act, requesting the agency to take or refrain from taking action with respect to any matter subject to its jurisdiction.

The Commissioner advises that such petitions will be the subject of explicit provisions in the new procedural regulations that will be published in the FEDERAL REGISTER in the near future. Accordingly, no provision is included in these regulations relating to such matters.

13. Questions have been asked as to whether data and information contained in a request for hearing on such matters as a food standard regulation, a food additive regulation, or withdrawal of a new drug application, are available for public disclosure.

The Commissioner advises that this matter will also be handled in the new procedural regulations that will be published in the FEDERAL REGISTER in the near future. As a general rule, such data and information have the same status as they would if they had been submitted as part of a petition or application of the type involved in the proceeding.

14. Requests have been made for all internal memoranda and other documents supporting some particular proposed or final regulations issued by the Food and Drug Administration.

The Commissioner advises that this matter will also be handled in the proposed new procedural regulations to be published shortly in the FEDERAL REGISTER. Accordingly, no provision with respect to this matter is included in these final regulations.

SECTION 305 HEARING RECORDS

15. Section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335) provides for an informal hearing before the Food and Drug Administration reports any violation of the Federal Food, Drug, and Cosmetic Act to a United States attorney for prosecution. Section 1.6(c) of the proposed regulations makes available for public disclosure factual information contained in the file relating to a hearing held under section 305 after the file is closed or the statute of limitations runs, whichever occurs first.

The basic objection to § 1.6(c) voiced in several comments was fear of what was variously termed "trial by newspaper" or "trial by press." It was argued that the effect of making public a section 305 citation would be to stigmatize a company without providing the company an opportunity for a public defense. This would be particularly true, it was asserted, if the section 305 hearing resulted in a determination that there was no basis for criminal prosecution. It was felt that the need for the public to know was outweighed by the potential injury to the manufacturer generated by a possible public misunderstanding over the nature of a section 305 hearing. Several comments drew parallels between the section 305 hearing and a grand jury hearing, suggesting that the secrecy necessary for the latter to operate was also necessary for a section 305 hearing.

The Commissioner concludes that the legislative history of the Freedom of Information Act and the recent amendments shows that Congress considered the potential for harm caused by release to the public of government information and found it to be outweighed by the public's right to obtain this information. Section 1.6(c)(4) adequately protects the rights of individuals by providing for deletion of names of individuals who were considered for criminal prosecution but were not prosecuted from the disclosable material. The Constitution and the Freedom of Information Act protect the right of privacy only of individuals. Accordingly, § 1.6(c) does not provide for similar deletions of names of corporations.

16. Concern was expressed that the utility of the section 305 hearing, described in current Food and Drug Administration regulations as "private and informal" (21 CFR 1.6(a)), would be seriously impaired if the hearing file is publicly disclosed. In a private and informal setting, a manufacturer might be willing to admit unintentional technical violations of the act in order to place the full facts on the records. If there were to be free disclosure of such factual information, it was stated, it would close the mouths of the manufacturers and prevent the section 305 hearing from accomplishing its purpose.

The Commissioner has no reason to believe that disclosure of this information after the matter is closed would impair the utility of the section 305 hearing. The Commissioner concludes that disclosure of the section 305 hearing records after the matter is closed is particularly important where prosecution is not recommended, or is recommended but not filed, in order to assure a public accounting of the matter. Any regulatory matter must at some point in time be open to public scrutiny and public accountability.

17. One comment argued that the Freedom of Information Act exemption for "investigatory files" was dispositive and prevented the Food and Drug Administration from providing for even limited release of investigatory records. The case of "Frankel v. SEC," 460 F. 2d 813 (2d Cir. 1972), was cited as a bar to the disclosures provided for in § 1.6(c). In "Frankel," a shareholder sought the SEC investigatory files on a corporation against which the SEC had brought suit. Prior to the request for disclosure the suit had been concluded by a consent decree. The Court noted that one of the purposes of the exemption of investigatory files, as expressed in the House and Senate reports, was "* * * to keep confidential the procedures by which the agency conducted its investigation and by which it has obtained information" (460 F. 2d at 817) and

reversed the District Court decision which held that after the file was not being actively used for law enforcement purposes it was no longer subject to the investigatory file exemption.

The Commissioner notes that the exemptions from disclosure for which the Freedom of Information Act provides are discretionary, not mandatory. The Commissioner has concluded, as a matter of discretion, that these records should be available for public disclosure after the matter is closed or the statute of limitations runs, whichever occurs first. See "Rayner & Stonington, Inc. v. FDA," No. 68-1995 (E.D. Pa. 1969). The "Frankel" decision merely holds that, where an agency does assert the investigatory file exemption, it may properly do so even after the matter is closed. The Commissioner does agree that those portions of investigatory records that would reveal confidential investigative techniques and procedures will not be disclosed, and § 4.64(a)(5) of the regulations so provides.

18. Questions have been raised as to whether section 305 hearing records, or any other investigatory records, compiled with respect to the activity of an individual, e.g., a clinical investigator, will be released after a determination is made not to take regulatory action and the matter is closed.

The Commissioner advises that all such records will be released to the public in accordance with §§ 1.6(c) and 4.64 after the matter is closed. Names and other information that would identify the individual will be deleted. If records relating to a closed section 305 hearing for a specific individual are requested by name, they will also be released after deletion of identifying information.

19. There was criticism of the provision for the deletion of "statements of witnesses obtained through promises of confidentiality, names of individuals * * * and other confidential information" since these exemptions are not specifically provided for in the statute. It was also suggested that keeping secret the names of individuals against whom the Food and Drug Administration determines not to bring prosecutions is a misapplication of "Wisconsin v. Constantineau," 400 U.S. 433 (1971). It was asserted that one court has rejected the contention that "Constantineau" bars disclosure of names of persons against whom "no prosecution" decisions have been made by administrative agencies, "Wellford v. Hardin," 444 F.2d 21 (4th Cir. 1971). It was contended that the public has a right to know of and judge these kinds of decisions, particularly since strict criminal liability is involved.

The Commissioner concludes that the Food and Drug Administration, as a law enforcement agency, is entitled under the Freedom of Information Act to exempt from disclosure investigatory records compiled for law enforcement purposes, and may, under some circumstances, keep such records confidential after the enforcement action is completed. See, e.g., "Frankel v. SEC," 460 F.2d 813 (2d Cir. 1972); "Weisberg v. Department of Justice," 489 F.2d 1195 (D.C. Cir. 1973); "Aspin v. Department of Defense," 491 F.2d 24 (D.C. Cir. 1973). The Food and Drug Administration views nondisclosure of witness statements induced by a promise of confidentiality to be essential to its law enforcement function and finds that such statements are protected by the investigatory records exemption. "Other confidential information" refers only to confidential information within the meaning of the Freedom of Information Act, and the

regulation has been revised to so state. With regard to the nondisclosure of names of individuals, § 1.6(c) is clearly in accord with the holding in "Wisconsin v. Constantineau." "Wellford v. Hardin" is inapplicable since it dealt with the disclosure of names of persons to whom warning letters were sent in lieu of prosecution and therefore would apply to section 306 of the Federal Food, Drug and Cosmetic Act rather than to section 305. As discussed elsewhere in this preamble, all warning letters issued under section 306 of the act are immediately releasable to the public.

20. It was suggested that what was determined to be disclosable "factual information" might well not be strictly factual since "facts" as recorded may reflect the opinions and subjective evaluations of the recorder. Opinions and subjective evaluations would thus be indirectly available for public disclosure when investigatory records are released.

The Commissioner is ware that in some instances it may be difficult to distinguish between fact and opinion. An effort will be made to separate the two and to release under § 1.6(c) those portions of the section 305 hearing records which do not contain any subjective opinions, except where the Commissioner concludes, in his discretion, that release of such additional material would be in the public interest.

The Commissioner notes that the investigatory records exemption is discretionary, not mandatory. Accordingly, the Commissioner may determine to release opinions and subjective information if he concludes that it is in the public interest to do so. A new § 4.82 has been added to the final regulations explicitly to provide for such discretionary disclosure.

21. A question has arisen as to whether the names of Food and Drug Administration employees will be deleted from section 305 hearing records.

The Commissioner concludes that the names of all Food and Drug Administration employees will be disclosed, except in rare circumstances where it is concluded that disclosure of such names would be inconsistent with the other provisions of the regulations, e.g., it would endanger confidential sources of information. The Commissioner believes that the names of all government officials involved in any regulatory matter should ordinarily be a matter of public information. Section 4.32 of the final regulations states this policy.

22. Questions have also arisen as to whether the names of individuals will be deleted from section 305 hearing records if the matter results in criminal prosecution.

The Commissioner concludes that such names will not be deleted if those specific individuals were included in the criminal prosecution. The name and other information that would identify any individual in a section 305 citation but not subsequently prosecuted will be deleted in order to protect his privacy.

23. Questions have arisen as to whether all or any portion of section 305 hearing records may be disclosed before the matter is closed or the statute of limitation has run.

Although the Commissioner retains discretion to release such information before the file is closed, he concludes that this will be done only in rare circumstances where consideration of criminal prosecution is involved. Because a section 305 hearing raises the possibility of criminal prosecution, the Food and Drug Administration must take precautions to avoid prejudicial pretrial publicity. Accordingly, the Commissioner will only very rarely exercise his discretion to release such material before the file is closed or the statute of limitations runs, and only under circumstances that demonstrate a compelling necessity.

24. Questions have been raised with respect to the exact time at which section 305 hearing records become "closed."

The Commissioner advises that the Food and Drug Administration has adopted general guidelines to determine when section 305 hearing records are closed. These guidelines are set out in § 1.6(c) of the final regulations and discussed in paragraph 113 of this preamble.

25. Under the Freedom of Information Act amendments, the investigatory records exemption has been amended to read as follows:

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that the product of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

The Commissioner concludes that the policy stated in § 1.6(c) fully complies with this change in the law. Section 305 hearing records deal with possible criminal prosecution. The Food and Drug Administration must be careful to avoid prejudicial pretrial publicity with respect to criminal matters. See "United States v. Abbott Laboratories," 369 F. Supp. 1396 (E.D.N.C. 1973), rev'd No. 74-1230 (4th Cir. 1974). Accordingly, the Commissioner concludes that, except in rare circumstances, information should not be released from a section 305 hearing record before the matter is closed, in order to avoid interference with enforcement proceedings or prejudicing a person's right to a fair trial and an impartial adjudication.

The Conference Report No. 93-1380, dated September 25, 1974, on the Freedom of Information Act amendments indicates that the purpose of this revision of the law is to narrow some of the court decisions that had tended to expand the investigatory file exemption. The Commissioner notes that § 1.6(c) is considerably narrower than a number of the court decisions would permit, and that the agency has already concluded to exercise its discretion to release investigatory records when a case is closed. The information excluded from such release under the final regulations falls squarely within the provisions of the revised statutory exemption contained in the amendments.

OFFICIAL RECORDS AND INFORMATION

26. A number of questions have arisen as to when the Food and Drug Administration will permit an employee to testify in private litigation.

The Commissioner concludes that the primary obligation of Food and Drug Administration employees is to implement and enforce the laws subject to the agency's jurisdiction. The agency has no congressional mandate to aid private litigants. Accordingly, the Food and Drug Administration will ordinarily decline to permit agency employees to testify or otherwise participate in their official capacity in private litigation.

The Commissioner recognizes, however, that exceptions will exist to this rule. For example, the Commissioner will permit Food and Drug Administration employees to testify or participate in private litigation in instances where former Food and Drug Administration employees testify with respect to agency policy in a way that requires correction of the record to prevent an unjust result, or where private litigation is designed to achieve the same purpose that would be achieved by agency action and thus is concluded by the Food and Drug Administration to be in the public interest, or where the results of the private litigation may have a significant impact on Food and Drug Administration policy or action, or where Food and Drug Administration action resulted in the lawsuit. Section 4.1 of the regulations has been revised to state this policy, and has been divided into three sections and rewritten for editorial purposes.

GENERAL POLICY

27. A number of comments on the proposed regulations published in May 1972 related to the broad policy underlying and interspersed with the specific provisions.

The Commissioner concludes that a new Subpart B should be added to 21 CFR Part 4, to include such statements of general policy.

POLICY ON DISCLOSURE OF FOOD AND DRUG ADMINISTRATION RECORDS

28. Comments contended that the proposed regulations published in May 1972 improperly placed the burden for justifying nondisclosure on companies who have previously furnished information, while placing no burden upon the public to justify any compelling need or cogent reason for requesting the information.

The Commissioner advises that these comments accurately reflect the proposed and final regulations, and that those regulations in turn reflect the intent of Congress as embodied in the Freedom of Information Act. Under the law, any person is entitled to receive information unless it is subject to one of the stated exemptions. The law does not require that there be any justification whatever for such a request. Only where there is a request for discretionary release of exempt records, or for waiver of fees, does the justification for disclosure become relevant.

UNIFORM ACCESS TO RECORDS

29. In administering the Freedom of Information Act, the Food and Drug Administration has uniformly adopted the position that, if any record is available to any member of the public, it must be made available to all members of the public, with only very limited exceptions. This approach guarantees equal access to all information available from the Food and Drug Administration.

The Commissioner concludes that this general policy should be explicitly stated in the final regulations. Accordingly, a new § 4.21 has been added for that purpose.

30. Comments requested clarification of the statement to the effect that information in Food and Drug Administration files that has previously been made public "in an authorized manner" will be generally released to the public, and asked what would be considered an "unauthorized" manner.

The Commissioner advises that this phrase, and other similar language in the final regulations, is intended to exclude information that is "leaked" from agency files or otherwise disclosed in an unauthorized manner. Thus, if an internal memorandum is given to a member of the press without authorization and part of it is reproduced in the public media, the entire memorandum or even the portion that has been reproduced need not be made available for public disclosure. Any different policy would encourage unauthorized disclosures of agency material.

The Commissioner concludes that release by Congress of material that would not be disclosed by the Food and Drug Administration is nevertheless an authorized release, since Congress is authorized to release any information it wishes to release. Accordingly, any material obtained by Congress, i.e., by a committee or subcommittee, and subsequently authorized to be disclosed, automatically triggers the requirement that it be released for public disclosure by the Food and Drug Administration to any person who requests it.

31. Some comments indicated that it would be acceptable to have scientific information contained in Food and Drug Administration files furnished to scientists and scholars, but that it should not be furnished to the news media or others who might distort it.

The Commissioner advises that such a distinction is untenable under the Freedom of Information Act. If any such information is made available to one member of the public, it must be made available to all.

PARTIAL DISCLOSURE OF RECORDS

32. The Freedom of Information Act amendments specify that any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under the Freedom of Information Act.
The Commissioner regards this new provision as a statement of existing Food and Drug Administration policy under the proposed regulations, and existing case law. See "EPA" v. Mink," 410 U.S. 73 (1973). Accordingly, § 4.22 has been added to state this general policy:

The Commissioner concludes that, as a general rule, when a document contains some material that is disclosable and other material that is nondisclosable, it will be released with the nondisclosable material deleted unless the two types of material are so inextricably linked that it is not reasonably possible to separate them. In instances of this type, the Commissioner may also exercise his discretion pursuant to § 4.82 of the regulations to release the entire document, or to make only a minimum number of deletions, e.g., the names of individuals, in order to avoid release of a document that would not be meaningful or useful to the public.

REQUEST FOR EXISTING RECORDS

33. Questions have been raised as to what constitutes a request for records under the Freedom of Information Act.

The Commissioner advises that pamphlets, speeches, and other materials routinely prepared for public distribution are distributed free of cost to the public upon request and thus do not fall under the Freedom of Information Act and these regulations. It is the policy of the Food and Drug Administration to regard any request for records not routinely prepared for distribution to the public to be under the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and thus subject to the requirements of these new regulations. New § 4.23 clearly states this policy.

PREPARATION OF NEW RECORDS

34. Questions have been raised as to whether the Freedom of Information Act requires the creation of new records or documents that do not presently exist, in order to provide an adequate response to a request.

The Commissioner concludes that the Freedom of Information Act pertains only to existing records. It does not create an obligation to prepare new compilations of information or otherwise to create new documents in order to respond to an inquiry.

On occasion, a request for documents that presently do not exist may raise questions of sufficient public interest to justify the diversion of agency time and effort necessary to prepare new documents that will provide an adequate response. The Commissioner may exercise his discretion in this regard whenever he concludes that it is in the public interest to do so. New § 4.24 of the regulations reflects this policy.

35. In the past 2 years, several requests have been received which would involve compiling statistics, researching citations to FEDERAL REGISTER notices, and similar work by the Food and Drug Administration.

The Commissioner advises that the Food and Drug Administration ordinarily will not undertake the compilation of new statistical reports or legal research, or preparation of new computer programs, or similar work, except where such work would benefit the public generally and fits

within the priorities and objectives of the agency. Any decision to undertake such work is solely within the discretion of the Commissioner.

RETROACTIVE APPLICATION OF REGULATIONS

36. Comments contended that the Freedom of Information Act may not properly be applied on a retroactive basis to data and information supplied to the Food and Drug Administration prior to the enactment date of the statute.

The Commissioner concludes that the Freedom of Information Act applies to all data and information in Food and Drug Administration files, regardless of when it was submitted. New § 4.25 of the final regulations so provides.

INDEXES OF CERTAIN AGENCY RECORDS

37. The Freedom of Information Act amendments provide for the maintenance and distribution of current indexes providing identifying information with respect to final opinions by an agency made in the adjudication of cases, statements of policy and interpretations not published in the FEDERAL REGISTER, and administrative staff manuals and instructions to staff that affect members of the public.

The Commissioner has ordered preparation of appropriate indexes of this type. New § 4.26 has been added to the regulations stating that such indexes shall be available at cost upon request from the Food and Drug Administration Public Records and Documents Center (HFC-18), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20852.

Since all final agency opinions in the adjudication of administrative cases are published in the FEDERAL REGISTER, an index will contain a citation to each. Such matters include only adjudicatory decisions in contested cases on the denial or revocation of new drug applications and new animal drug applications, and not decisions in rule making proceedings such as food standards and antibiotic drugs. An index will also include all statements of policy and interpretation adopted by the agency since enactment of the various laws subject to the jurisdiction of the agency, not published in the FEDERAL REGISTER, and still in force. Finally, an index will cover all administrative staff manuals and instructions that contain directives that affect a member of the public, except those that contain only internal personnel rules and practices of the agency, which are specifically exempt from public disclosure under the Freedom of Information Act.

SUBMISSION OF RECORDS MARKED AS CONFIDENTIAL

38. Several comments contended that merely stamping documents submitted to the Food and Drug Administration as "confidential" or "privileged" or "trade secret material" would create a presumption of confidentiality or, at the very least, an obligation on the part of the Food and Drug Administration to review the material and to return it if the Food and Drug Administration disagreed with the requested status of the documents. In effect, the comments suggested that any

such designation would trigger a request for a presubmission review, and that the failure of the agency to respond to any such designation would automatically require the Food and Drug Administration to retain those documents in confidence.

The Commissioner disagrees with these comments. New § 4.27 explicitly provides that any such designation is inadequate to trigger a presubmission review for confidentiality, and that the acceptance by the Food and Drug Administration of documents so designated creates no obligation whatsoever on the part of the Food and Drug Administration with respect to their subsequent handling under the Freedom of Information Act. A presubmission review of records submitted voluntarily to the Food and Drug Administration, to determine whether they will be disclosed to the public on request, may be obtained under the provisions of new § 4.44.

FOOD AND DRUG ADMINISTRATION DETERMINATIONS OF CONFIDENTIALITY

39. A number of comments objected to requirements contained in several provisions in the proposed regulations that confidential information be specifically marked "confidential" upon submission, and that such claims to confidentiality be justified in advance of any request for the information. It was contended that this would be a massive amount of paperwork, much of which may be needless.

The Commissioner agrees with this comment. Most determinations for confidentiality are already spelled out in the form of specific provisions in the final regulations and in this preamble, and many of the remainder will be settled by the new procedure for presubmission review specified in § 4.44 of the final regulations. Where close questions arise, moreover, § 4.45 will be utilized to permit consultation with the affected person. Accordingly, the final regulations do not require that data or information be stamped as confidential or that justification for confidentiality be submitted. Indeed, under § 4.27 of the final regulations, stamping material as confidential will have no effect whatever. New § 4.28 provides that the status of all records will be determined solely by the regulations and any presubmission review that is requested.

PROHIBITION ON WITHDRAWAL OF RECORDS FROM FOOD AND DRUG ADMINISTRATION FILES

40. Situations have frequently arisen within the past 2 years in which persons who have voluntarily submitted information without a written pledge of confidentiality by the Food and Drug Administration have objected to release of the documents involved or have requested that the disputed documents be returned to them.

The Commissioner notes that new § 4.44 makes it clear that any information voluntarily submitted without a written pledge of confidentiality pursuant to the procedures contained in that provision may be disclosed to the public unless the Commissioner concludes that it falls within one of the exemptions set out in the Freedom of Information Act and these implementing regulations and that he should not exercise his discretion to release the information involved. Under no circumstances will the Food and Drug Administration return any document submitted to it. The only circumstances under which any document will not be retained by the Food and

Drug Administration is where pursuant to new § 4.44, there is a presubmission review, the Food and Drug Administration concludes that the information will not be accepted as confidential, and the person declines to submit the information on that basis and requests that it be returned to him instead. New § 4.29 makes this policy clear.

FOOD AND DRUG ADMINISTRATION PUBLIC RECORDS AND DOCUMENTS CENTER

41. The Freedom of Information Act amendments embody a congressional mandate for greater agency accountability for compliance with the provisions of the Freedom of Information Act.

The Commissioner has established a Public Records and Documents Center to be responsible for the agency's compliance with the Freedom of Information Act. All requests for records will be submitted to this Center, and all responses will be coordinated by it. Section 4.30 of the final regulations so provides.

PERMANENT FILE OF REQUESTS FOR FOOD AND DRUG ADMINISTRATION RECORDS

42. In order to permit public review of information previously disclosed under the Freedom of Information Act, the Food and Drug Administration maintains a permanent file of all requests and responses. This file is available for public review during working hours.

The Commissioner concludes that a new § 4.31 should be added to the final regulations stating this policy.

DISCLOSURE OF FOOD AND DRUG ADMINISTRATION EMPLOYEE NAMES

43. Questions frequently arise as to whether the names of Food and Drug Administration employees contained in various agency records will be deleted prior to disclosure of such records.

The Commissioner concludes that, except in extraordinary circumstances, the names of all government officials involved in any regulatory matter are properly disclosed to the public. New § 4.32 states this policy. Only in unusual circumstances, such as where the identity of a confidential source would be disclosed if the name of the agency employee involved in the matter were also disclosed, will be the name of the agency employee be deleted before the requested records are made available for public disclosure.

PROCEDURES AND FEES

44. The Freedom of Information Act amendments contain a number of provisions pertaining to procedures and fees. In addition, the proposed regulations published in May 1972 contained several provisions relating to procedures and fees, and the Commissioner concludes that they should be set out in one place for ready reference.

Accordingly, the commissioner is adding a new Subpart C to 21 CFR Part 4, relating to procedures and fees.

FILING A REQUEST FOR RECORDS

45. The Freedom of Information Act amendments state that, upon any request for records which reasonably describes such records and which is made in accordance with published rules, the records shall be made promptly available.

The Commissioner concludes that this policy should be clearly stated in a new § 4.20, along with directions on where to file a request for any Food and Drug Administration record.

TIME LIMITATIONS

46. The publication of rules stating the time, place, fees (if any) and procedures to be followed by the public in requesting records pursuant to the Freedom of Information Act is important for the proper implementation of that law.

The Commissioner concludes that all requests for Food and Drug Administration documents shall be made in writing to the Public Records and Documents Center (HFC-18), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Such requests will be logged in at the time, and in the order they are received. The time at which a written request is logged in at that office shall determine the beginning of any time requirements. Oral requests for documents will not trigger any time requirements. Written requests sent elsewhere within the agency will not trigger any time requirements until they are redirected to the Public Records and Documents Center and are logged in there. This is the only way in which an accounting of all public information requests can accurately be made.

47. The recommendations of the Administrative Conference of the United States, the regulations of the Department of Health, Education, and Welfare, and the Freedom of Information Act amendments all provide that the agency determine within 10 days, excepting Saturdays, Sundays, and legal public holidays, after the receipt of any request whether or not to comply with that request, and if not, immediately notify the person making the request of such determination, the reasons therefor, and the right of such person to appeal any adverse determination. The Freedom of Information Act amendments provide for an extension of the 10-day time period in "unusual circumstances," and define that phrase.

The Commissioner has included in § 4.41 of the final regulations, provisions implementing this concept. Within 10 days of receipt, a determination will be made whether, or to what extent, the information will be released, except in unusual circumstances. As soon as possible after that determination is made and required prepayment is furnished, the disclosable material will be forwarded or made available to the person requesting it.
The Commissioner anticipates that in most instances the specific provisions of these final regulations, together with the explanatory discussion in this preamble, will clearly determine whether the material is disclosable.

48. A number of comments on the proposed regulations asked for clarification of the procedure under which responses are made and persons are required to furnish payment before receiving the requested records.

The Commissioner agrees that a specific procedure should be included in the regulations and a new provision in § 4.41 has been added for this purpose. Within the 10 days required for response to a Freedom of Information Act request, an estimate will be made of the cost of providing the requested records that are available and the response will contain that estimate. If the cost can be determined accurately ahead of time and is greater than $25, the response will state that the records will be sent or made available upon receipt of the amount of money specified or estimated. If the person requesting the information wishes to proceed and sends the prepayment, the material will be obtained and forwarded as quickly as possible.

The Commissioner concludes that records should not be furnished until the money is actually received, since otherwise there would be no way to guarantee that fees will in fact be paid. Situations have arisen during the past 2 years where the Food and Drug Administration has gathered documents at agency expense in response to a request under the Freedom of Information Act, only to be informed that the expense involved was too high.

FEES

49. The proposed regulation published in May 1972 contained uniform standard charges at or slightly below the cost of the activity to the Food and Drug Administration. It also provided for waiver of fees on the basis of indigence. Criticism of the fee schedule was made by several groups in comments filed on that proposal. One comment indicated that copies should cost no more than the few cents per page they cost the agency. The $5.00 fee for certification of authenticity was thought to be out of line and it was suggested that the charge be 50 cents, the amount charged for that service by the United States District Court for the District of Columbia. It was contended that there should be a threshold fee, below which there is no charge. It was suggested that the fees, as proposed, would act as a deterrent to legitimate requests for disclosure.

Upon reconsideration, the Commissioner has modified the fee schedule in some respects. The fees charged by the Department of Justice (16 CFR 16.9) and the Department of Health, Education, and Welfare (45 CFR 5.61) have been used as a model. The charges, as modified, are slightly less than the actual cost to the agency. Under the Federal User Charges Act (31 U.S.C. 483a), and in accordance with the policy of the Federal government, these costs must be passed along to those who seek services from the agency. This system should not act as a deterrent to legitimate requests for disclosure.

50. Comments requested that the fees for copying be reduced to five cents per page.

The Commissioner advises that the cost to the government for copying is in excess of 10 cents per page. Accordingly, the Commissioner concludes that a fee of 10 cents per page is reasonable.

51. Numerous questions have been raised with respect to the fee required for a computer printout of information that is available in this form.

The Commissioner advises that fees for computer printouts will be assessed at actual cost. No standard fee can be calculated, because of the different factors that must be considered with respect to each request. Section 4.42(a)(3) states this policy.

52. Comments also urged that the hourly fee for search not be charged for administrative time spent in deciding whether to grant access to information and suggested that this be explicitly stated in the regulations.

The Commissioner advises that the hourly fee is to be charged exclusively for actual time spent in determining what records are requested, locating those records, and copying them. It will be the policy of the Food and Drug Administration not to charge for time spent by legal counsel or others in determining which information must be disclosed pursuant to the Freedom of Information Act. This policy is reflected in § 4.42(b) of the final regulations.

53. Questions have been raised as to how a check or money order for documents should be made payable, and to whom it should be sent within the Food and Drug Administration.

The Commissioner advises that all checks or money orders should be made payable to the "Food and Drug Administration." The term "United States" or the initials "U.S." should not be included. Checks or money orders are to be mailed to the Accounting Operations Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Section 4.42(c) of the final regulations states these requirements.

WAIVER OF FEES

54. Many different circumstances have been brought to the Commissioner's attention to justify a waiver of fees.

As a General principle, the Commissioner concludes that waiver or reduction of fees should not be granted except under circumstances of indigence, or where it will benefit the public broadly, or where it involves another component of the federal government or a state government. Thus, information furnished to a congressional committee, a federal agency, a state or local agency, a court, or a foreign government, will ordinarily be furnished without cost.

The Commissioner has also determined that the cost of obtaining payment for a small number of records, in terms of government time and effort involved, exceeds the revenue obtained from this effort. Accordingly, the final regulations provide that no fee will be charged where the specific request and any related requests involve a cost of less than $5.00.

55. Comments stated that the regulations should include a definition of "indigence" and "strong public interest necessary to justify a waiver of fees." It was suggested that the customary

definition of indigence, "unable to afford the fee without deprivation of the necessities of life," ignores the needs of most nonprofit and citizens' groups. The following test was suggested:

1. The requester purports to represent the consumer and general public interest.

2. The requester is a nonprofit organization exempted from payment of Federal income taxes by the Internal Revenue Service.

3. It generates no profits and, except in connection with its charitable activities, sells no goods or services.

4. It receives its funds solely from one or more of the following sources: Membership dues, contributions from the general public, and from other charitable organizations, and grants and contracts with government agencies.

5. It has no uncommitted funds available at the time of the request for payment of the fees from which it seeks relief by waiver.

The Commissioner notes that the Federal User Charges Act (31 U.S.C. 483a) and the Freedom of Information Act do not make any distinction between industry, citizens' groups, professional associations, and individuals. All who can pay must bear the cost of covered services provided to them by the Federal government.

The Commissioner concludes that the test of indigence suggested in the comments is insufficient to demonstrate that release of the information requested will primarily benefit the general public. Under the test suggested in the comment, any request that even purports to be in the general public interest would be sufficient to justify a waiver of fees.

The Commissioner concludes that a definition of indigence based on the definition of this term used by state and federal courts in determining who may proceed in forma pauperis should be adopted for purposes of these regulations. Section 4.43(b) sets out the considerations that will be used in determining indigence.

56. The Freedom of Information Act amendments provide that documents shall be furnished without charge or at a reduced charge where the agency makes a discretionary determination that waiver or reduction of the fee is in the public interest because furnishing the information can be considered primarily as benefitting the general public.

The Commissioner advises that a new paragraph (c) has been added to § 4.43 of the final regulations to implement this provision.

The Food and Drug Administration has in the past received a substantial number of open-ended requests for documents from individuals and organizations purporting to represent the consumer and general public interest. For example, requests have been made for all data and information in Food and Drug Administration files relating to the safety of cosmetics, and for all "Dear

Doctor" letters required by the Food and Drug Administration to be sent to physicians to correct misleading advertising and labeling. It is apparent that, if all such requests were honored without the requirement of fees, the agency would soon be engulfed by similar requests for information from large numbers of individuals and organizations, and that a major portion of its time would be spent answering such inquiries.

Thus, in applying this new provision, the Commissioner will require a demonstration of a broad public interest before fees will be waived or reduced. As part of this demonstration, the Commissioner will request a statement of the intended purpose to which the information will be put, in order to determine whether it is likely to be used in a manner that will benefit the public generally. Narrow and specific requests for documents will be far more likely to satisfy this standard than will broad fishing expeditions requesting large numbers of vaguely described documents covering a wide range of issues. In making a determination of the public interest involved, the Commissioner will weigh the agency resources involved against the likely benefit to the public.

The Commissioner wishes to assist any inquiry that will genuinely advance the public interest. If this is to be done, however, the very limited resources available in the Food and Drug Administration for this purpose must be devoted to those requests that demonstrate the greatest likelihood of useful public service. The Commissioner intends to utilize this authority to encourage requests for information that will broadly promote the public interest.

57. Questions have arisen as to whether fees will be assessed when the records requested are not found or are withheld from public disclosure.

The Commissioner advises that no fees will be assessed under these circumstances. This policy is stated in new § 4.43(d).

PRESUBMISSION REVIEW OF REQUESTS FOR CONFIDENTIALITY OF VOLUNTARILY SUBMITTED DATA OR INFORMATION

58. Section 4.26 of the proposed regulations contained a provision permitting any person who wishes to submit information voluntarily to the Food and Drug Administration to request an initial determination as to whether it will be held in confidence or will be disclosed upon request to the public. The comments submitted on the proposal, and numerous questions that have arisen in the intervening 2 years, have made it clear that this provision has not been well understood by those who reviewed the proposal.

Accordingly, the Commissioner concludes that this provision should be the subject of a separate procedural regulation and expanded to clarify its intended application. Section 4.44 has been added to the final regulations to accomplish this purpose.

The Commissioner concludes that any person who wishes to submit information on a voluntary basis to the Food and Drug Administration is entitled to a presubmission determination of the status of the documents involved if that status is not already determined by other provisions in

the regulations. Merely labeling a submission as "confidential" is insufficient to trigger this provision and raises within the Food and Drug Administration no obligation to consider the status of the documents at that time or to return the information or otherwise to communicate with the person submitting it. Similarly, oral assurances of confidentiality by Food and Drug Administration employees will not be honored. If this procedure is to be invoked, it must be done in strict accordance with the requirements of new § 4.44. The Commissioner realizes that this is a stringent procedure but concludes that this is the only way that these matters can be handled in fairness both to persons submitting information and to the members of the public who subsequently request the information involved.

The Commissioner emphasizes that this procedure is not available where the status of a record is already determined by other provisions in the final regulations, and especially § 4.111 *Data and information submitted voluntarily to the Food and Drug Administration.* For example § 4.111(d)(2) states that no information on manufacturing processes is available for public disclosure, and thus presubmission review of any such information would be unnecessary and inappropriate.

59. Comments expressed concern that, although there is validity in the concept of permitting the Food and Drug Administration to accept information in confidence that it would not otherwise obtain, procedures should be spelled out to preclude abuse of this provision.

The Commissioner agrees with this comment. Accordingly, the final regulations provide that such information may be accepted in confidence only if it is relevant to and important for agency activity, and only if the Assistant Commissioner for Public Affairs signs a letter pledging confidentiality. A determination of confidentiality cannot be given orally or by any other agency official.

60. Comments pointed out that, if information submitted voluntarily on a pledge of confidentiality is already contained in other Food and Drug Administration records which are not exempt from disclosure, those other records should be disclosed to the public.

The Commissioner advises that, under these circumstances, a determination of confidentiality will not be made. If a determination of confidentiality is mistakenly made, the information already available in the Food and Drug Administration files will, if it is not otherwise exempt from disclosure, promptly be disclosed upon request.

61. Many comments indicated the need for a "meaningful" appeal procedure that would go to the highest level within the agency and to the courts, with provision for a stay of disclosure to permit the commencement of an appeal process.

The Commissioner agrees that an appeal procedure and a stay of disclosure pending appeal is reasonable, where the issues present a close question. Appropriate procedures have been incorporated in §§ 4.44 through 4.46 for this purpose.

SITUATIONS IN WHICH CONFIDENTIALITY IS UNCERTAIN

62. Proposed § 4.33 stated that, where disclosure is uncertain, the Food and Drug Administration will consult with the person who submitted the information in making a determination whether it will be disclosed. This proposed provision has been included in the final regulations as § 4.45.

Comments stated that industry should be notified in all instances, not just in situations where the Food and Drug Administration is uncertain about disclosure. This section was also criticized because it does not make clear who decides when disclosure of data is uncertain, and whether such an "uncertain" status is created only with regard to previously submitted material or whether it also applies to newly submitted material.

The Commissioner concludes that the Food and Drug Administration will notify the submitting person only when it determines that there is some question as to the status of the material. There are many instances in which the material is clearly disclosable under the law and these implementing regulations, and it would be burdensome and wasteful to contact the person who had submitted it under such circumstances.

A decision as to whether or not the status of the data is "uncertain" and therefore subject to § 4.45 will be made by those administratively responsible for making disclosures. Such a decision will be made, if necessary, with the assistance of legal counsel.

Uncertainty about the status of information voluntarily submitted on which presubmission review is requested is the subject of separate provisions in new § 4.44.

63. Comments suggested that a company should be advised whenever any record is to be released for public disclosure pursuant to the Freedom of Information Act if that record was either submitted by the company or refers to the company.

The Commissioner rejects this suggestion. Any such procedure would severely hinder implementation of the Freedom of Information Act. Section 4.45 of the final regulations provides for consultation with affected persons wherever a close issue arises, and § 4.46 permits an affected person to seek court review in such instances.

The Commissioner advises that the final regulations adequately state the basis on which disclosure will be made to the public in the future. The proper remedy for any person to pursue, in the event that he has submitted data or information in the past which he believes to be confidential but which, under the final regulations, is included within a category for which public disclosure is permitted, is to bring a declaratory judgment action contesting the validity of the regulations. Unless these regulations are successfully challenged in the courts, the Food and Drug Administration intends to implement them. Thus, all person who have previously submitted records to the Food and Drug Administration are hereby put on public notice that such information will be handled in the future as set out in these final regulations and this preamble. For this reason, specific notice to a person that a particular record will be disclosed pursuant to these regulations is unnecessary as well as impracticable.

64. Comments contended that this provision shows the high value that the Food and Drug Administration puts on industry interests in information as opposed to the public welfare. Some interpreted this provision as the Food and Drug Administration asking to be persuaded that the information is confidential. It was suggested that, in situations where it has not been conclusively established that the information falls squarely within an exemption to the Freedom of Information Act, the information should be disclosed.

The Commissioner regards these comments as reflecting a lack of understanding of the law. The exemptions under the Freedom of Information Act relate to such important issues as personal privacy and valuable trade secrets. Congress has directed Federal agencies to consider these matters and the Commissioner regards this responsibility as important. In utilizing this provision, the Food and Drug Administration will seek clarification in uncertain situations, not persuasion. If information does not fit within any exemption to the Freedom of Information Act, it will be disclosed.

JUDICIAL REVIEW OF PROPOSED DISCLOSURE

65. A number of questions have been raised with respect to the right of a person to obtain a court determination before the Food and Drug Administration discloses data or information submitted by that person which he believes should be retained by the agency in confidence.

During the past 2 years the Commissioner has adopted a procedure of permitting any person who believes he would be adversely affected by disclosure of information to institute suit in a United States District Court to enjoin such disclosure. The Commissioner has stated that, if any such suit is instituted, no disclosure will be undertaken until all court appeals are exhausted. The Commissioner believes that this procedure adequately balances the right of the public to obtain information against the right of a person to protect the confidentiality of material that he believes should not be publicly disclosed. Accordingly, new § 4.46 of the final regulations includes this procedure.

The Commissioner cautions that this does not mean that the Food and Drug Administration must in every instance advise persons who might be affected by a disclosure of information that such information has been requested by a member of the public. The Food and Drug Administration will exercise its judgment in determining when close issues exist that may give rise to this procedure. The Commissioner believes that experience during the past 2 years has demonstrated that proper judgment in these matters can readily be exercised.

DENIAL OF A REQUEST FOR RECORDS

66. The Commissioner concludes that specific provisions should be made in the final regulations for the procedure to be followed upon denial of any request for records. The Freedom of Information Act amendments provide that the names and titles or positions of each person responsible for the denial of a request for information shall be set forth in the letter denying the request.

Accordingly, new § 4.47 has been added to the regulations to accomplish these purposes.

NONSPECIFIC AND OVERLY BURDENSOME REQUESTS

67. Section 4.35 of the proposed regulations, which dealt with nonspecific and overly burdensome requests, has been redesignated as § 4.48 in the final regulations.

A few comments were concerned that the proposed regulations were not sufficient to prevent "fishing expeditions." It was emphasized that the Freedom of Information Act, as well as the Attorney General's Memorandum interpreting it, makes information available only in response to a request for identifiable records. It was noted that the courts have upheld the requirement that those seeking disclosure under the act provide a reasonable description of the records to enable government employees to locate the documents citing "Irons v. Schuyler," 465 F. 2d 608 (D.C. Cir. 1972); "Bristol-Myers Co. v. FTC," 424 F. 2d 935 (D.C. Cir. 1970).

The Commissioner notes that many cases, as well as the Freedom of Information Act amendments, require only that documents be described, not that they be specifically identified. Section 4.40(b) of the final regulations states this requirement. A request must be made with sufficient specificity to permit the Food and Drug Administration to determine what information is requested and to obtain it. However, merely because a request is nonspecific or broad does not mean that the records requested are not identifiable. For example, a request for all of the documents in a particular category is a broad, nonspecific request, yet such records would be easily identified. If a request is so vague that it is difficult, if not impossible, to determine which records the request seeks, the agency will seek clarification.

68. A comment objected to this provision on the ground that the Freedom of Information Act provides for no such balancing of public interest against administrative efficiency, and contended that there is no justification for any provision dealing with "overly burdensome" requests, citing "Wellford v. Hardin," 444 F. 2d 21 (4th Cir. 1971).

The Commissioner advises that this provision is intended to emphasize the need for specific requests, rather than general requests for large numbers of documents that are often not relevant to the immediate interests of the person making the request, and to point out that responding to requests for large numbers of documents may require a substantial period of time. The Commissioner notes that the Freedom of Information Act amendments provide only that the person making a request be informed within 10 days whether part or all of the documents will be disclosed. No statutory time limit is established for actual production of the documents themselves. This indicates recognition by Congress that government employees cannot be expected to drop all other duties in order to respond to requests for information . There is no indication, in short, that Congress intends the Food and Drug Administration to handle freedom of information requests on a higher priority basis than its important law enforcement duties.

On the other hand, the Commissioner does not intend that requests under the Freedom of Information Act receive a low priority or simply be ignored. They will be handled as expeditiously as is feasible. Sections 4.41 and 4.48 of the final regulations so provide.

REFERRAL TO A PRIMARY SOURCE OF RECORDS

69. Comments on the proposed regulations asked what documents will be distributed without charge pursuant to the regulations. In particular, questions were raised about the status of documents such as the Code of Federal Regulations (CFR), FEDERAL REGISTER, United States Pharmacopeia (U.S.P.), and National Formulary (N.F.).

The Commissioner notes that there are a wide variety of materials, including press releases and educational materials, which are prepared by the Food and Drug Administration for distribution to the public. These will continue to be released and distributed without charge.

It is the policy of the Food and Drug Administration that if anyone is charged for a document, all must be charged unless the fee is waived pursuant to these regulations. Conversely, if a document is routinely given free of charge, then all must receive it free of charge.

Two of the documents referred to in the comments, i.e., CFR and the FEDERAL REGISTER, are available from the Government Printing Office. The other two, U.S.P. and N.F., are available from the organizations that publish them. Since none of these are Food and Drug Administration materials and all are readily available elsewhere at a price lower than it would cost the Food and Drug Administration to reproduce them, it is the policy of the Food and Drug Administration to refer anyone who requests them to those places where they are available, pursuant to § 4.49 of the final regulations.

AVAILABILITY OF RECORDS AT NATIONAL TECHNICAL INFORMATION SERVICE

70. In a number of instances, the Food and Drug Administration has recognized that reports or information generated or received by the agency will receive widespread interest. The Department of Commerce has established the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22152, to serve as a clearinghouse for such information. The Food and Drug Administration is, for example, sending all scientific literature reviews and reports of the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology to NTIS for reproduction and distribution to the public, as announced in the FEDERAL REGISTERS of July 26, 1973 (38 FR 20054), April 17, 1974 (39 FR 13796), and September 23, 1974 (39 FR 34218).

The Commissioner concludes that, when documents are furnished to NTIS, a single copy will be available for public review at the Food and Drug Administration. All requests for copies of such documents will be answered by referring the person requesting the copies to NTIS. The Commissioner concludes that this approach fully satisfies the requirements of the Freedom of Information Act. Section 4.50 of the final regulations states this policy.

USE OF PRIVATE CONTRACTOR FOR COPYING

71. A comment suggested that, rather than charge for copying or sending information to an independent contractor for copying, information in Food and Drug Administration files that is

available for public disclosure should be loaned to the person who is requesting it who can then copy it himself.

The Commissioner concludes that lending material for copying usually will not be permitted. The Food and Drug Administration has had difficulty with loss of materials from files in the office of the Hearing Clerk. The Food and Drug Administration would have no way to determine whether materials loaned to individuals would be returned intact. Only where materials requested are contained in bound volumes and their safe return can be assured would this possibly be feasible. The Commissioner concludes that no change in the final regulations is warranted to handle these situations.

REQUESTS FOR REVIEW WITHOUT COPYING

72. Numerous requests have been received by the Food and Drug Administration during the past 2 years for an opportunity to review specified documents without the necessity of copying them. Such requests have pointed out that copying is expensive and that on occasion only a few, if any, of the requested documents might be relevant to the person's needs. Copies would then be requested only of those documents which, after a personal review, are determined to be relevant.

The Commissioner advises that this procedure is entirely acceptable to the Food and Drug Administration except where a record involved contains both disclosable and nondisclosable material. Under those circumstances, the only feasible way to make the record available for inspection is to copy it without the nondisclosable material blocked out. Accordingly, a new § 4.52 is added to the final regulations to state this policy.

INDEXING TRADE SECRET AND CONFIDENTIAL COMMERCIAL OR FINANCIAL DATA AND INFORMATION

73. In recent court decisions, it has been suggested that, upon judicial review of an agency decision to deny documents or portions thereof, the agency may be required to itemize and index the disputed material in order to permit adequate judicial consideration of the issues.

The Commissioner concludes that, where records or portions thereof are denied on the basis of the exemption for trade secrets and confidential commercial or financial data and information, the matter is subsequently contested in the courts, and the court orders such itemization and indexing, the Food and Drug Administration will require that this be undertaken by the person affected, i.e., the person who submitted the documents. The Food and Drug Administration will also request that the person affected intervene to defend the trade secret status of the disputed documents. The failure of the affected person to itemize and index such disputed documents and to defend their status will constitute a waiver of any trade secret defense, and the Food and Drug Administration will promptly make them available for public disclosure. Section 4.53 states this policy.

The Commissioner concludes that the burden of defending the trade secret status of disputed documents is properly placed upon the affected person, because this status inures only to the benefit of that person. The Commissioner concludes that it should not be encumbent upon the

government to defend the property right of a person in such a matter, and that, in any event, the person affected is in the best position to present a trade secret defense to the court.

EXEMPTIONS

74. The Freedom of Information Act provides that all government records and documents shall be made available to the public upon request, except for the following nine specific types of information:

1. (A) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order.

2. Related solely to the internal personnel rules and practices of an agency.

3. Specifically exempted from disclosure by statute.

4. Trade secrets and commercial or financial information obtained from a person and privileged or confidential.

5. Interagency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency.

6. Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

7. Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel.

8. Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

9. Geological and geophysical information and data, including maps, concerning wells.

Of these nine exemptions, the four relating to trade secrets, internal memoranda, personal privacy, and investigatory files are of particular importance to the Food and Drug Administration.

In the proposed regulations published in May 1972, the provisions relating to these four exemptions were interspersed with a number of other sections relating to other matters. The Commissioner concludes that, for purposes of clarity, the provisions of the final regulations relating to those exemptions should be separated from the other sections and placed in a separate new Subpart D of Part 4.

75. Questions have arisen as to whether documents that are not available from the Food and Drug Administration because of the applicability of one of the exemptions, e.g., trade secrets, may be obtained directly from the company or other person who has submitted them.

The Commissioner advises that this procedure is entirely acceptable, and encourages companies and other persons submitting information to the Food and Drug Administration to make such exempt material available.

APPLICABILITY OF EXEMPTIONS

76. Numerous comments on the proposed regulations suggested that each of the available exemptions should be repeated as possibly applicable in every particular section dealing with the status of particular types of documents, e.g., correspondence and written summaries of oral discussions.

The Commissioner notes that § 4.36 of the proposal provided that nondisclosable portions of documents will be deleted from otherwise disclosable material before it is made public. It is apparent, however, that this provision was not clearly understood by many who reviewed the proposal. Accordingly, the Commissioner is placing this provision in new § 4.60, the first section in Subpart D of Part 4 dealing with exemptions, and has revised it more clearly to state the policy that each exemption is to be considered in determining whether all or any part of otherwise disclosable records should be deleted before making the records available to the public.

77. It was suggested in comments on the proposed regulations that, if deletions of confidential information are to be made, only the company is capable of making all necessary deletions. Frequently, it was stated, just the association of a trade name of a product with a certain composition may be a breach of confidentiality. In many records a complete rewriting would be necessary other than a simple deletion because confidential material may be interwoven with nonconfidential material.

The Commissioner advises that, where there is some uncertainty as to the confidential status of the material, the person who submitted it will, under § 4.45, have the opportunity to indicate which portions of a record he believes should be exempt. However, the person who submits material does not under any circumstances have the final say on what will and will not be deleted.

TRADE SECRETS AND COMMERCIAL OR FINANCIAL INFORMATION THAT IS PRIVILEGED OR CONFIDENTIAL

78. By far the most extensive comments on the proposed regulations related to the definitions of "trade secret" and "confidential data or information" in proposed § 4.25, and the specific application of these definitions with respect to particular information received in petitions and applications as reflected in the proposed amendments to Parts 8, 121, 130, 135, and 146.

Numerous comments pointed out that the regulations must reflect the interaction of three statutes. The general Federal confidentiality statute, 18 U.S.C. 1905; the confidentiality provision in section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)); and the exemption under the Freedom of Information Act for "trade secrets and commercial or financial information that is privileged or confidential" (5 U.S.C. 552(b)(4)). The Commissioner notes that the preamble to the proposed regulations referred to all three statutes, and that the proposal was intended to reflect the congressional policy embodied in them.

The general Federal confidentiality statute, 18 U.S.C. 1905, provides that:

Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment.

Section 301(j) of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 331(j)) prohibits:

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, 512, 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

The Commissioner concludes that the Freedom of Information Act trade secrets exemption is as least as broad as, and is perhaps somewhat broader than, the confidentiality provisions of the other two statutes. The major difference between them is that, whereas the Freedom of Information Act exemption is discretionary, the other two statutes embody mandatory requirements. Disclosure of information prohibited by the other two statutes constitutes a criminal offense. Accordingly, to the extent that the other two confidentiality statutes apply, disclosure of trade secrets and confidential commercial or financial information by the Food and Drug Administration is wholly prohibited by Federal law. Even if such disclosure would be in

the public interest, in order to protect the public health, and even if the Commissioner wishes as a matter of discretion to release such material, such disclosure cannot lawfully be undertaken.

The Commissioner concludes that it is not feasible or practical to determine the differences, if any, between the confidentiality provisions in 18 U.S.C. 1905 and 21 U.S.C. 331(j), and in the Freedom of Information Act . If there are any differences, they are extremely subtle and small. Accordingly, the Commissioner intends, for practical reasons of daily administration of the law, to regard the coverage of these provisions as identical. This will have the effect of prohibiting any discretionary release of documents that fall within the trade secrets and confidential commercial information exemption to the Freedom of Information Act . The Commissioner concludes that to do otherwise would invite confusion, lead to arbitrary decisions, and raise the possibility of violation of the criminal sanctions contained in the two mandatory Federal confidentiality statutes.

The Food and Drug Administration has on numerous occasions testified before Congress that current statutory prohibitions prevent disclosure of useful information contained in the agency's files, and particularly, data relating to the safety and effectiveness of drugs. The Food and Drug Administration cannot change the law; and thus is bound by the present provisions until Congress acts.

79. One comment discussed at length the Commissioner's citation of 18 U.S.C. 1905, the general Federal confidentiality statute, contending that this statutory provision was intended by Congress to be solely a "remedial" provision and does not represent substantive law. It argued that 18 U.S.C. 1905 has no application unless the information sought falls within one of the exemptions to the Freedom of Information Act , and that 18 U.S.C. 1905 is not itself an exemption to the Freedom of Information Act , citing "Frankel v. SEC," 336 F. Supp. 675 (S.D.N.Y. 1971); "Schapiro v. SEC," 339 F. Supp. 467 (D.D.C. 1972). It was suggested that 18 U.S.C. 1905 may properly be read to provide for criminal penalties for disclosure of information only when such disclosure is specifically prohibited by another statute, and to read 18 U.S.C. 1905 as an exemption to the Freedom of Information Act would, in effect, nullify the act and such could not have been the intent of Congress.

The Commissioner believes that this issue is moot, in view of the fact that the confidentiality provisions in 21 U.S.C. 331(j) and the trade secret exemption from the Freedom of Information Act cover the same type of information. The Commissioner also advises, however, that he does not concur with the legal interpretation provided by the comment. The comment did not cite any other confidentiality provision in Federal law that does not carry with it a sanction against release of the confidential information. Accordingly, if 18 U.S.C. 1905 were read solely as a remedial statute, to provide sanctions for disclosure of information that is prohibited by other sections of the law, it would be wholly meaningless. The only way to give this provision of the law true meaning is to read it as a general Federal prohibition against disclosure of trade secret information. This is the interpretation adopted by the Attorney General's Memorandum on the Freedom of Information Act . In any event, is not necessary to resolve this legal question in this instance because of the separate confidentiality requirements in the Federal Food, Drug, and Cosmetic Act and the Freedom of Information Act .

80. A large number of comments questioned the use of the definition of a trade secret in section 757 of the Restatement of Torts. The comments argued that this definition was intended for purposes of litigation, to establish commercial damages, and thus is an inappropriate definition for harmonizing the competing values of an "open society" with adequate protection of trade secrets. The comments stated that the regulations should be sensitive to a "right of privacy" of a manufacturer and should recognize that information furnished by industry to the Food and Drug Administration is subject to a property right. Under the approach suggested in these comments, the key to a question of confidentiality would be whether the company intended the information to be confidential and whether it had, in fact, so treated the information, not whether there is a competitive use for the information.

The Commissioner concludes, upon review of the comments and the relevant case law, that the Restatement definition of a trade secret should remain the basic guideline for application of this exemption from the Freedom of Information Act . The Supreme Court has recently noted that the Restatement definition of a trade secret is "widely relied-upon," "Kewanee Oil Co. v. Bicron Corp.", 94 S. Ct. 1879 (1974). The Commissioner can find no reason why it should be utilized for determining commercial damages but not for purposes of the Freedom of Information Act .

The Commissioner agrees that there is a property right reflected by the trade secret exemption from the Freedom of Information Act . He concludes that new § 4.61 adequately reflects that right.

The Commissioner does not agree that the intent of the person who submits documents to the Food and Drug Administration controls, or is even relevant to, the question whether those documents may be released to the public upon request under the Freedom of Information Act . The Freedom of Information Act establishes specific exemptions, which are to be applied by objective criteria. The subjective standard proposed in the comments would result in little or no disclosure of information to the public, contrary to the clear intent of Congress.

81. Comments suggested that the official Restatement Comment on the definition of trade secrets be included as part of the Food and Drug Administration regulations. Comment (b) to section 757 of the Restatement of Torts states that:

An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and to his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

The Commissioner agrees that the official Comment on the Restatement definition is helpful in understanding the intended meaning of the definition. This Comment neither broadens nor narrows the definition itself, but simply elucidates the various factors encompassed within that

definition. The Commissioner concludes that it is unnecessary to include this comment as part of the definition in the final regulations, but advises that these factors will be considered in applying the definition set out in the regulations.

82. The definition of a trade secret as set forth in the proposed Uniform Trade Secret Protection Act was suggested as a possible alternative definition by several comments:

*Any formula, pattern, device or compilation of scientific, technical, or commercial information which the trade secret owner has taken reasonable precautions to maintain in secrecy so that except by the use of improper means there would be difficulty in acquiring it, and which gives said owner an opportunity to obtain an advantage over others who do not know or use it *** Matter which otherwise constitutes a trade secret will not lose its status as such if it is disclosed by the trade secret owner to and accepted by an outsider in confidence ****

The Commissioner concludes that there is no significant difference between this definition and the Restatement definition. Both place primary emphasis upon competitive advantage.

83. A number of comments cited case law dealing with trade secrets for the proposition that any technical or scientific information developed by a company may be considered a trade secret where it is not generally known or readily ascertainable and when it is protected and maintained as confidential by the developer and is of value to him.

The Commissioner agrees with this general statement of the case law, and concludes that the definition set out in § 4.61 of the final regulations adequately reflects it. In the Commissioner's opinion, the concept of commercial and competitive values is fully recognized by the courts.

84. Other comments contended that the Restatement definition of a trade secret is far too broad. One suggested that the controlling definition of trade secret in connection with the release of information should be the one noted in "Consumers Union v. Veterans Administration," 301 F. Supp. 796, 801 (S.D.N.Y. 1969), appeal dismissed, 436 F. 2d 1363 (2d Cir. 1971):

**** an unpatented, secret, commercially valuable plan, appliance, formula, or process, which is used for the making, preparing, compounding, treating, or processing of articles or materials which are trade commodities.*

Information contained in a new drug application concerning animal and clinical testing, it was asserted, would not be a trade secret under this definition.

The Commissioner notes that the court in the "Consumers Union" case did not attempt an all-inclusive definition of a trade secret for purposes of all Federal law. It used a judicial description found in a 1925 case that arose under the predecessor statute of 18 U.S.C. 1905. There is no reason to consider that definition controlling for purposes of the Freedom of Information Act . Moreover, even this definition does not exclude clinical data since such data can properly be considered as part of a "plan" or a "process".

85. Comments stated that the Restatement definition of trade secret is inadequate because it does not include a crucial element required in the common law of trade secrets in order to prove damages, i.e., the requirement that improper means be employed in obtaining the information.

The Commissioner concludes that the common law requirement that improper means be employed to obtain a trade secret in order to prove damage is comparable to the requirement included in the proposed and final regulations that information cannot be regarded as trade secret if it has been previously disclosed in a lawful manner to any member of the public. Accordingly, no modification in the definition in the final regulations is warranted.

86. Several comments took the position that, while the Restatement definition indicates that the information must give an individual an opportunity to obtain an advantage over competitors, the language in the second paragraph 5 of the preamble to the proposal seemingly excluded any information which is not currently providing a manufacturer with a competitive advantage and thus narrowed further was already a narrow definition of trade secrets.

The Commissioner concludes that information which provided a manufacturer with a competitive advantage in the past, but is not currently providing a competitive advantage and will not, in all likelihood, do so in the future, is not covered by the Restatement definition and does not fall with the trade secrets exemption. If the information is not currently providing a competitive advantage the Food and Drug Administration will make a determination as to the probability of a future competitive advantage. Paragraph 5 of the preamble to the proposal indicated that the Food and Drug Administration has made some conclusions from past experience as to the probability of future competitive advantage with regard to safety, effectiveness, and functionality data. If a manufacturer can show in a particular case that, because of extraordinary circumstances, these data will provide a future competitive advantage, they will not be made available for public disclosure.

87. Several comments pointed out that the statutory exemption for trade secrets actually extends to two separate types of information, trade secrets and confidential commercial information, and that while, in theory, these two were treated as separate entities in the proposal, by relying solely upon the criterion of competitive advantage the two were in fact merged together into one narrow exemption. It was urged that the Restatement definition is only adequate to deal with the concept of "trade secret" and is not relevant in determining whether or not information was "confidential". It was again suggested that the manner in which information was treated was of greater importance in determining its confidential nature than the immediate use of the information. It was suggested that the regulations be amended to provide a separate type of exemption for confidential information that does not rely upon the concept of competitive advantage.

Other comments emphasized that there was no exemption for confidential information per se and that the exemption applies only to confidential information that is commercial or financial in nature.
The Commissioner concludes that, under the relevant statutes, trade secrets and confidential commercial or financial information are two separate categories of exempt information, and that

there are different criteria for each. This is reflected in the separate definitions for each given in § 4.61 (a) and (b) of the final regulations. If information falls within either paragraph (a) or (b) it will be considered exempt. However, it should be noted that the matter of competitive advantage is often significant in determining whether commercial information is confidential within the meaning of § 4.61(b) since confidential information per se is not exempt, but only confidential information that is commercial or financial in nature.

88. Numerous comments discussed an appropriate definition for "commercial or financial information" that is "privileged or confidential". Some argued that this would include all information which a company regards as confidential and uses in the course of its business, and others contended that it should apply only to such clear financial information as data relating to sales and profits.

The Commissioner has reviewed the legislative history of the Freedom of Information Act and has concluded that this phrase is properly interpreted on a narrow basis. If it were interpreted broadly, as suggested by some comments, it would make the trade secrets exemption irrelevant, and indeed would largely undermine the philosophy of the Freedom of Information Act. The legislative history indicates that this portion of the exemption was intended to apply to information customarily held in strict confidence, such as business sales statistics, inventories, customer lists, manufacturing processes, and technical or financial data submitted to obtain a loan, as well as to information customarily subject to the doctor-patient and lawyer-client privileges. The Commissioner believes that the provisions of 18 U.S.C. 1905 and 21 U.S.C. 331(j) are properly interpreted in the same way. Accordingly, the Commissioner has revised the final regulations to reflect his approach to the matter.

89. There was objection to the dependence of a confidential status upon whether or not the information was of a type "customarily held in strict confidence or regarded as privileged." The issue, it was asserted, was whether a particular record or document was in fact, held in confidence.

The Commissioner does not agree with this comment. If the confidential status of commercial information depended solely upon the way that each individual manufacturer handles information in his own business, decisions under the Freedom of Information Act would be highly inconsistent and would require the Food and Drug Administration to conduct an ad hoc inquiry into the way that each manufacturer handles documents submitted to the agency. Such an approach is neither practicable nor contemplated by the law.

The Commissioner notes that the legislative history shows that Congress intended that commercial and financial information submitted to the government would be handled according to the customary and usual practice in the industry rather than according to the way that any particular firm regards it. Thus, it is customary to expect that the doctor-patient and lawyer-client privilege will be respected, whereas many other forms of commercial information are not customarily held in confidence.
In this respect, the criteria for a trade secret and for confidential commercial information are substantially different. The former depends entirely upon the competitive advantage attributable

to the specific information involved, whereas the latter may be applicable even if there is no specific competitive advantage involved if such information is generally held in strict confidence according to usual industry practice. In both instances, of course, lawful prior public release of the information automatically destroys the confidential status of the information.

90. Comments asserted that the need for the public disclosure of safety and effectiveness data is so great that no justification of trade secret or confidential commercial status was sufficient to withhold such information.

The Commissioner concludes that it is Congress which weighs the need for the release of certain information against the need for retaining it as confidential. With regard to trade secrets, Congress has concluded that the need to withhold such information outweighs the need to release it. The Freedom of Information Act expressly makes an exemption for this type of information and other statutes provide for criminal penalties for releasing it.

91. Comments suggested that language covering manufacturing and quality control procedures be added to this provision in the final regulations even though it is specifically dealt with in other provisions.

The Commissioner advises that § 4.61 is intended to serve as a general definition, and not to catalog all information that may have trade secret status. The fact that it does not mention a particular type of information does not mean that information is not a trade secret.

92. One comment contended that the fact that more than one manufacturer in an industry may know of and use an ingredient does not lessen the competitive advantage that accrues to those manufacturers who know and use the ingredient as opposed to all other manufacturers in the industry. The comment also argued that it is frequently impossible for any manufacturer to know whether any of his competitors has become aware of his use of a particular ingredient.

The Commissioner concludes that use of an ingredient by more than one manufacturer for the same purpose is not, in itself, sufficient to justify a conclusion that such use is not a trade secret. The Commissioner recognizes that whether the use of an ingredient constitutes a trade secret will depend upon a number of factors, and primarily whether it has previously been disclosed to the public as defined in § 4.81 of the regulations. A representation by a company that, to the best of its knowledge and belief, the ingredient has not previously been disclosed to any member of the public, will be sufficient to create a prima facie case of confidentiality, which may be rebutted by the Food and Drug Administration if it determines that the ingredient has in fact become public knowledge.

93. Comments asserted that the release of information under the proposed regulations would result in claims against the government based on "Padbloc v. United States," 161 Ct. Cl. 369 (1963) and "Bofors v. United States," 153 F. Supp. 397 (Ct. Cl. 1957).

The Commissioner concludes that, since the Freedom of Information Act requires release of information not specifically exempt, and no contract is involved, no claims may properly be

made against the government under the "Padbloc" case. The Commissioner notes that the "Padbloc" and "Bofors" cases involved a breach of contract in a commercial venture with the government and thus are not relevant here.

94. Comments suggested that a manufacturer's assertion that specified information is either a trade secret or confidential commercial information not be overruled unless "clearly erroneous." It was also suggested that a final determination be subject to judicial review on the weight of the evidence as a whole, since otherwise there would be too severe a burden of persuasion for the company in court to overturn an incorrect determination by the Food and Drug Administration.

The Commissioner concludes that the Freedom of Information Act does not permit the Food and Drug Administration to accept a manufacturer's assertions of confidential status without careful scrutiny of each claim. Moreover, under the Freedom of Information Act the courts are obligated to "determine the matter de novo" and the burden is on the agency to sustain any denial of records.

95. A question has arisen as to whether information that has been made public through a patent can nevertheless be classified as a trade secret.

The Commissioner concludes that all information made public through a patent will be available for public disclosure and that the trade secrets exemption will under no circumstances be applicable to any such information.

96. A comment contended that information which may fall within the trade secrets protection cannot be divulged without notice, hearing, and judicial review, citing "American Sumatra Tobacco Corp. v. SEC," 93 F.2d 236 (D.C. Cir. 1937).

The Commissioner concurs with the substance of this comment. Notice and an opportunity to present comments on the rules to be utilized in determining when the secret secrets exemption applies were furnished by the proposed regulations published in May 1972. The possibility of judicial review has been extended, with rare exception, to affected persons when disclosure is contemplated by the Food and Drug Administration in situations where the facts present a close question. Upon the receipt of any further comments and any modifications of these regulations as provided in this final order, judicial review will be available through a declaratory judgment action challenging the final regulations or a declaratory judgment action in accordance with § 4.46 challenging the proposed release of specific records. Accordingly, the Commissioner concludes that the general principles laid down in the "Sumatra" case are fully satisfied.

INTER- AND INTRA-AGENCY MEMORANDA OR LETTERS

97. Section 4.27 of the proposed regulations, which dealt with the internal memorandum exemption from the Freedom of Information Act, is redesignated as § 4.62 in the final regulations.

Comments stated that the term "memoranda" is unclear. Questions were asked whether it refers to all written communications, including an investigator's report, or only to a document entitled

"memorandum." It was suggested that the preamble should state the criteria for determining whether or not a document is a "memorandum."

The Commissioner advises that the term "memoranda" refers to all written communications and not just to those documents bearing the title "memorandum." The legislative history of the Freedom of Information Act reveals that this was the intended congressional meaning of the term. Section 4.62 has been revised accordingly.

98. One comment contended that if the explanatory portions of an internal agency memorandum are deleted and the remainder is disclosed, the "factual" information may be reported out of context. It was suggested that, because of this consideration, all portions of agency memoranda should be exempt. It was also suggested that, since it is frequently difficult to distinguish between "fact" and "conclusion," some clarification of the term "factual information" would be helpful. It was stated that "factual information" should be defined to include factual analysis and materials which can be considered surveys and studies.

The Commissioner notes that the intra-agency memorandum exemption applies only to opinions, recommendations, or policy discussions within the deliberative processes of an agency. The courts have held that an entire agency memorandum that includes both factual information and opinions is not exempt from disclosure unless fact is so interwoven with opinion that the two cannot be separated. The Commissioner intends to make liberal use of his discretion to disclose internal memoranda reflecting policy discussions, with deletion only of trade secret data and material relating to personal privacy, wherever this can be done without disrupting the agency's activities. In all other instances the agency will do its best to distinguish between "fact" and "opinion." The Commissioner concludes that it is neither necessary nor practical to define the term "factual information." The dividing line between fact and opinion must be made on a review of the specific material in question.

99. Comments contended that the agency, by not disclosing agency memoranda while at the same time disclosing written communications from private external sources, creates the possibility of presenting a distorted view. For example, damaging communications from and to a firm could be disclosed while data contained in intra-agency memoranda relevant to a full understanding of the situation would be withheld.

The Commissioner advises that he intends, wherever feasible, to exercise his discretion to release internal agency memoranda in order to avoid the possibility of a distorted view. In any event, the factual portions of internal memoranda are clearly disclosable unless they cannot reasonably be separated from the policy portions.

100. In a number of instances, requests have been received by the Food and Drug Administration for disclosure of internal memoranda analyzing data or information submitted to the Food and Drug Administration. Such memoranda invariably contain both factual information and opinions and recommendations, and the two very seldom are or can be separated. Moreover, even the way that the factual information is presented may well reflect the internal opinions and views of the Food and Drug Administration staff.

The Commissioner concludes that, as a general rule, such internal summaries of data and information will not ordinarily be disclosed if the underlying data and information are available for public disclosure. Thus, an analysis of food additive safety data, all of which are available for disclosure, usually will not be made public. Where the underlying data and information are not available for public disclosure, however, the Commissioner either will exercise his discretion to release the entire analysis with appropriate limited deletions, such as names of patients, trade secrets, and statements that would represent an unwarranted invasion of privacy, but disclosing all of the deliberative and policy discussion, or will, at the very least, make available the document with the factual information intact and all of the deliberative and policy discussion deleted. Thus, as discussed elsewhere in this preamble, the Commissioner has concluded to make available for public disclosure internal memoranda summarizing the safety and effectiveness data contained in previously approved new drug applications, with deletions only of the limited type mentioned above, since the underlying safety and effectiveness data are themselves not publicly available. This general approach to the handling of internal agency summaries has recently received judicial approval in "Montrose Chemical Corp. v. Train," 491 F.2d 63 (D.C. Cir. 1974).

101. It is frequent practice for the Food and Drug Administration to prepare a summary of comments received on proposed regulations or objections received on final regulations, for purposes of internal decisionmaking. Requests have been made for copies of such summaries.

The Commissioner concludes that such summaries are internal memoranda that ordinarily will not be made available for public disclosure. Such summaries usually combine both factual information and conclusions and policy recommendations. The underlying documents on which the summary is based are all available for public disclosure. The courts have recently ruled that such summaries are therefore exempt from disclosure pursuant to the internal memorandum exemption, "Montrose Chemical Corp. v. Train," 491 F.2d 63 (D.C. Cir. 1974).

102. Weekly reports are prepared by Food and Drug Administration field offices for submission to the Executive Director for Regional Operations in Washington. Requests have been made for such reports.

The Commissioner advises that such reports are internal memoranda that are explicitly exempt from disclosure under the Freedom of Information Act. Although they contain some factual information that may be disclosable, they also contain conclusions and recommendations relating to policy that are not disclosable.

The Commissioner advises that, in order to promote free and open discussion between field personnel and headquarters, it is not feasible to make these reports available for public disclosure on a routine basis. The factual information contained in any specific report may well be available for public disclosure if it does not otherwise fall within in an exemption from the Freedom of Information Act, and the Commissioner will also consider release of any specific report on a discretionary basis if good cause is shown for such release.

CLEARLY UNWARRANTED INVASIONS OF PERSONAL PRIVACY

103. A comment wanted to know the exemption to the Freedom of Information Act upon which the deletion of names from records is based. The comment stated that names or identifying characteristics may be deleted from "personnel and medical files" only if disclosure would produce a "clearly unwarranted invasion of privacy." Whether or not an invasion of privacy is clearly unwarranted must be decided on a case-by-case basis. "Getman v. NLRB," 450 F.2d 670 (D.C. Cir. 1971) was cited for the proposition that an agency must "balance the right of privacy of affected individuals against the right of the public to be informed, and the statutory language 'clearly unwarranted' instructs [an agency] to tilt the balance in favor of disclosure", 450 F.2d at 674.

The Commissioner advises that he bases the deletion of names upon both the privacy exemption under the Freedom of Information Act and general principles pertaining to the right to privacy under common law and the Constitution. The Freedom of Information Act exempts from disclosure all medical and personnel files, and similar files the disclosure of which is a clearly unwarranted invasion of personal privacy. The agency has concluded that the release of any names contained in a medical file is clearly unwarranted, except in extraordinary circumstances. A possible exception to this general conclusion might arise if an issue of fraud were involved. Similarly, names of individuals involved in criminal investigations will be deleted if no criminal charges are brought, in order to prevent unfair accusations.

104. Many questions have been asked about the relationship between proposed § 4.31 and the related provisions in proposed § 4.26(f). It was contended that they are to some extent inconsistent or, in any event, require clarification, since proposed § 4.31 provided for public disclosure of the identity of any person who writes to the Food and Drug Administration and proposed § 4.26(f) provided for deletion of the name of the person reporting adverse reaction and complaint information.

The Commissioner agrees that these two provisions require clarification, and appropriate modifications have been made in the final regulations. The Commissioner advises that, pursuant to § 4.111(c)(3)(i) of the final regulations, all consumer letters and other communications received from lay persons, which relate to their own personal complaints, will be made public after deletion of names and other identifying information, in order to protect their privacy. With respect to complaints received voluntarily from third parties, usually health professionals, i.e., doctors, nurses, pharmacists, and so forth, relating to such matters as adverse reactions they have observed, and which thus relate to complaints made on behalf of other persons, the Commissioner concludes on the basis of the longstanding experience of the Food and Drug Administration that it is essential to pledge that all identifying information will be deleted prior to public disclosure, and § 4.111(c)(3)(iii) so provides. If such a pledge is not made, the possibility of persuading health professionals voluntarily to submit important adverse reaction information on marketed products to the Food and Drug Administration is substantially diminished, and indeed perhaps wholly destroyed. Such information is important to the Food and Drug Administration and to the public, since it may well lead to action by the Food and Drug Administration designed to protect the public health. Accordingly, the Commissioner concludes

that deletion of all such identifying information from such reports prior to release to the public is fully within the intent of the personal privacy and confidential commercial information exemptions.

105. Comments stated that, even though a specific request for confidentiality may not be made, consumer complaint letters may contain documents which are per se confidential. Some complaints contain medical records which were obtained by a patient's written release to doctors or hospitals. Such medical records may be confidential or such medical release may imply the confidentiality of the entire complaint. Release of medical records of complainants may violate the doctor-patient relationship of confidentiality. The comments pointed out that the Freedom of Information Act exempts medical files of government employees from disclosure, and urged that this same privilege be extended to all letters containing such material which are submitted to the Food and Drug Administration.

The Commissioner advises that such medical records are seldom enclosed with a consumer complaint. However, if the Food and Drug Administration receives medical records of a complainant, they will be held as confidential even if the complainant makes no specific request for confidentiality, except that they may be disclosed to the complainant.

106. Comments on various provisions in the proposed regulations contended that manufacturer and product names be accorded the same treatment as individual names. It was urged that corporations be permitted to require the Food and Drug Administration to keep their identity confidential if they submitted a particular piece of information voluntarily. Comments requested that the requirement of a showing of "extraordinary circumstances" for nondisclosure of corporate names be deleted. Other comments argued, however, that a manufacturer should never be permitted to make a showing of "extraordinary circumstances" to justify nondisclosure of his identity.

The Commissioner concludes that the same treatment should not be given to corporate and product names as to individual names. The right to privacy applies only to individuals. If a corporation requests presubmission review of information it wishes to submit voluntarily pursuant to § 4.44, and makes a claim of confidentiality for the manufacturer or brand name which is rejected by the Food and Drug Administration, the corporation has the option of withdrawing that information.

The Commissioner concludes that the final regulations properly provide for a showing in a particular instance that a manufacturer or product name constitutes confidential commercial information and thus, under § 4.61, is properly deleted from a record before it is made available for public disclosure.

107. Comments contended that the name of the investigator in a test or research project should be deleted where the report of the test or project is otherwise disclosable, in order to prevent a clearly unwarranted invasion of his personal privacy.
The Commissioner does not agree with this comment. The investigator is the person who is responsible for conducting the test or study. Names of investigators are customarily published in

the scientific literature with a summary of their work, and an investigator's curriculum vitae customarily refers to the research projects in which he has participated. Accordingly, the Commissioner concludes that disclosure of the name of the investigator on a particular project is neither a clearly unwarranted invasion of personal privacy nor confidential commercial information.

108. Questions have arisen as to whether the Food and Drug Administration will divulge all agency records relating to a specifically named individual, without that individual's consent.

The Commissioner advises that any such request is regarded as a clearly unwarranted invasion of personal privacy. A "fishing expedition" of this type will therefore not be permitted. In the event that a specific record relating to a specific individual is requested, it will be released in accordance with the various provisions established in the final regulations.

109. Comments suggested that § 4.31(b) of the proposed regulations, which stated that the identity of patients should not be disclosed in IND and NDA submissions, more properly belongs in other portions of Food and Drug Administration regulations.

The Commissioner concurs that this provision should be added to other Food and Drug Administration regulations, but believes that the principle should also be stated in Part 4. Accordingly, § 4.63(b) of the final regulations states this policy in general terms.

INVESTIGATORY RECORDS COMPILED FOR LAW ENFORCEMENT PURPOSES

110. The proposed § 4.32, dealing with investigatory records, has been redesignated as § 4.64 in the final regulations.

The Commissioner notes that a number of comments and questions specifically directed to § 1.6(c) of the regulations, dealing with section 305 hearing records, are also generally applicable to other investigatory records compiled by the Food and Drug Administration for law enforcement purposes. Accordingly, the conclusions of the Commissioner stated in this preamble are equally applicable to § 4.64 of the final regulations, and appropriate conforming modifications have been made in § 4.64.

111. Numerous questions have been raised with respect to specific documents that will or will not be made available pursuant to the investigatory records exemption.

Each of the specific types of letters, reports, forms, worksheets, and other documents prepared or used by the Food and Drug Administration in the course of its regulatory activities has been reviewed in detail by the Commissioner, in light of the exemption for investigatory records. The proposed regulations published in May 1972 took a very open disclosure policy, and provided for disclosure even where the law permitted retention of records as confidential. Implementation of that proposal during the past 2 years has demonstrated that even greater disclosure would not harm the regulatory activities of the agency. Accordingly, the Commissioner has concluded that the final regulations should continue the broad disclosure policy reflected in the proposal, and

indeed should provide even greater release of such information. Thus, as discussed in relation to § 4.101, all records relating to administrative enforcement action will be released even though they may also be part of an investigatory file.

The sole exception to this rule applies where the possibility of criminal prosecution is under active consideration. As discussed above in this preamble, considerations of interference with enforcement proceedings and the right of an individual to a fair trial and an impartial adjudication lead the Commissioner to conclude that section 305 hearing records should not be released until the matter is closed. These same considerations apply to all investigatory records pertaining to a matter that is under active review with respect to possible criminal prosecution.

This exception only applies, however, with respect to such records while criminal prosecution is under active and current consideration. The Commissioner recognizes that any records in any file within the Food and Drug Administration may at some point lead to, or become part of, a criminal prosecution. This is plainly an insufficient justification for retaining all such material as confidential. Thus, it is fully anticipated that in some instances investigatory records will be released before any serious consideration of criminal prosecution even though criminal prosecution is later considered and in fact instituted. The Commissioner concludes that this anomaly cannot be avoided if there is to be a policy in favor of the greatest possible disclosure of information to the public. The Commissioner believes that any disruption of enforcement proceedings by adherence to this policy will be insubstantial, and that there will be no adverse impact whatever on the right to fair trial and impartial adjudication.

The Commissioner has also considered these matters in light of the revision of the investigatory records exemption contained in the Freedom of Information Act amendments. It is the Commissioner's conclusion that the final regulations fully meet the standards set out in that revision and thus that the regulations do not require further change.

112. Comments contended that the release of investigatory records after a matter is closed is directly contrary to the Food and Drug Administration's prior position as expressed in Mamana, "FDA's Obligations Under the 1966 Public Information Act," FDA Papers, Sept. 1967 at page 18:

It is also reasonable to conclude that the indiscriminate distribution of FDA investigative files to the public would result in a carte blanche interpretation of the facts contained in such files. This would not be in keeping with the principles of fair play and justice to those regulated.

The Commissioner advises that, since the publication of that article, there has been a reevaluation of the release of such information to the public. Whether or not to claim a particular exemption is discretionary and, in this instance, the agency has exercised its discretion in favor of greater disclosure. Experience during the past 2 years has demonstrated that this will not jeopardize the agency's law enforcement efforts. The Commissioner therefore concludes that disclosure of this material is entirely proper.

113. A comment contended that, in order to justify the use of the investigatory records exemption, there must be a concrete prospect of enforcement proceedings, citing "Bristol-Myers

v. FTC," 424 F. 2d 935 (D.C. Cir. 1970). It was urged that, after an inspection has been made, the Food and Drug Administration should have 3 months to decide whether or not to institute proceedings. If a decision is made not to institute proceedings or if no decision is made within 3 months, the files should be opened. The comment stated that the 5-year statute of limitations would destroy all attempts to examine or understand Food and Drug Administration compliance activities within the last 5 years, which is clearly not the intent of the Freedom of Information Act.

The Commissioner concludes that it is appropriate to establish internal guidelines for determining when a matter is "closed." No arbitrary time period can properly be established. In very few, if any, instances will disclosure of investigatory records be delayed until the statute of limitations runs. A decision on action is normally made within the Food and Drug Administration within a relatively short period of time. Only where a decision is made to take legal action and the action results in protracted preparation or litigation will the matter normally remain open for any lengthy period of time.

The Commissioner advises that investigatory records will be available as soon as the decision is made not to take action on the specific matter involved in that record. To make this intent clearer, § 4.64 has been revised to replace the word "file" with the word "record." This is consistent with the Freedom of Information Act amendments, which make the same change in the statutory language. Thus, although a Food and Drug Administration file remains open on a continuous basis, and records on which no action has been taken in the past may well be the subject of future action where there is a continuing problem, individual records will be released at the earliest possible moment.

The Commissioner advises that, except in unusual circumstances, a record will be considered closed following:

1. *Inspection*, when:

a. The report, as endorsed by the supervisor, shows either no action is indicated (NAI), or in compliance (IC), and there are no samples in the process of being analyzed which are related to the inspection. If samples are being analyzed, the file remains open until the samples are determined to be not actionable (NAI).

b. The report is endorsed as a voluntary action indicated (VAI), and a subsequent decision is made by higher review authority that no action will be taken (NAI).

NOTE: The issuance of a letter to the company has no bearing on the status of the matter.

2. *Sample collection*, when:

a. The district office concludes the sample is not actionable (NAI), whether or not the sample was analyzed.

b. A decision is made by higher review authority that the sample is not actionable (NAI), based on the sample results.

c. Any legal action involving the sample is completed.

NOTE: Results of analyses or worksheets shall be given to a firm on request and thus are available to the public on request.

3. *Regulatory letter*, when:

A response has been received which has been verified to show the violations were corrected, and no further action is contemplated.

NOTE: The regulatory letter itself and any correspondence relating to it or documents given to the company are available to the public as soon as they are issued.

4. *Seizure*, when:

a. A decision is made not to forward the case to a United States attorney (PA).

b. A final decision is made by the Department of Justice not to file the case.

c. The seizure has been adjudicated, time for appeal has passed, and no further action (criminal or civil) is contemplated using that sample. This coincides with permanent abeyance (PA) of the case.

NOTE: Court papers field in connection with a seizure are available to the public when filed, unless directed otherwise by the court.

5. *Section 305 citation*, when:

A final agency decision has been made to seek no further action on the matter (PA). If further review of the matter is requested, the matter remains open until a decision is made by the reviewing office to close the case with no further action. If prosecution is sought, the matter remains open until that action is concluded.

NOTE: Providing a copy of the memorandum prepared by the Food and Drug Administration summarizing the hearing to the citee or his attorney, to assure the accuracy of the record, does not require release of that memorandum to the public.

6. *Prosecution*, when:

a. A decision is made not to forward the case to a United States attorney (PA).
b. A final decision is made by the Department of Justice not to file the case.

c. The case is adjudicated and time for appeal is past.

NOTE: Court papers filed in connection with a prosecution are available to the public when filed, unless directed otherwise by the court.

7. *Injunction*, when:

a. A decision is made not to forward the case to a United States attorney (PA).

b. A final decision is made by the Department of Justice not to file the case.

c. The case is adjudicated and time for appeal is past.

NOTE: Court papers filed in connection with an injunction are available to the public when filed, unless directed otherwise by the court.

8. *Recall*, when:

A decision has been made not to pursue criminal or civil action, based on the recall. This may be some time after the recall is completed, or shortly after it begins. The point is reached whenever the decision is made.

NOTE: Information on each recall is immediately released to the press, specific press releases may be issued on certain recalls, and all correspondence with the firm is available to the public upon request.

9. *Imports*, when:

a. A refusal of entry has been issued. The fact of detention is public information as soon as the detention is made, but the file does not become available until after there is an opportunity for an informal hearing, a final refusal of admission is made, and all litigation is concluded.

b. The product has been released into commerce.

LIMITATIONS ON EXEMPTIONS

114. A number of the regulations in the May 1972 proposal relate to limitations on the exemptions from the Freedom of Information Act, i.e., exceptions to the usual rules of nondisclosure.

The Commissioner concludes that these limitations should properly be grouped together in a separate new Subpart E of Part 4, for purposes of clarity.

APPLICABILITY LIMITATIONS ON EXEMPTIONS

115. Comments requested clarification on the extent to which a record that is ordinarily exempt from public disclosure could nonetheless be disclosed by the Food and Drug Administration to limited categories of persons without invoking the rule that a record must be available to all members of the public if it is available to anyone.

The Commissioner advises that the Freedom of Information Act specifically recognizes certain categories of persons and situations where a record may be disclosed without making it generally available to all members of the public. Section 4.80 sets out those circumstances where disclosure of a record will and will not require general disclosure to the public. For example, when the Commissioner concludes to exercise his discretion pursuant to § 4.82 to disclose an internal memorandum that he would otherwise be authorized to withhold from disclosure, that record must be available to any member of the public who requests it. If the Commissioner discloses that internal memorandum to Congress or to another Federal agency, however, disclosure to the public is not required.

DATA AND INFORMATION PREVIOUSLY DISCLOSED TO THE PUBLIC

116. Section 4.28 of the proposed regulations, which provided that data and information previously made available to the public will not be regarded as confidential by the Food and Drug Administration, has been redesignated as § 4.81 in the final regulations.

A number of comments stated that the proposal was too restrictive and indicated that there may be situations in which trade secret information is furnished in confidence to individuals other than employees or paid consultants, e.g., confidential disclosures to clinical investigators or potential or actual licensees, or during discovery, or to other government agencies, or to health authorities outside the United States. It was suggested that the applicant himself may have received the information under contract from a third party. It was further suggested that the provision be revised to contain the following language:

For purposes of these regulations, such data and information will not be deemed to have been disclosed to the public if it is disclosed by the owner thereof on a confidential basis and with appropriate restrictions on its disclosure or use.

The Commissioner agrees that there may be other legal arrangements between business associates under which such disclosure of trade secrets is entirely appropriate and would not destroy the confidentiality of the information involved. Section 4.81 of the final regulations so provides. Disclosure to a limited number of unpaid consultants solely for purposes of the consultation involved is specifically permitted.

117. Comments stated that the mechanics for determining whether there has been prior public disclosure of a submission are unclear. It was suggested that a statement be required, subject to the False Reports to the Government Act (18 U.S.C. 1001), for all information previously submitted.
The Commissioner concludes that a statement with respect to prior disclosure will be requested only when the Food and Drug Administration concludes that the issue is relevant to a question of

disclosure. It would not be feasible to require such a statement for all information previously submitted to the agency, and any such requirement would be wasteful because much of the previously submitted information is unlikely ever to be requested.

118. A comment contended that the policy as stated in the preamble seems more restrictive than as stated in the proposed regulation, i.e., the preamble refers to disclosure by the manufacturer, while the proposed regulation refers to disclosure by "any person."

The Commissioner advises that lawful disclosure to the public by any person is sufficient to destroy the confidentiality of the information. Disclosure of material only in an unlawful way, e.g., stolen material, will not destroy its confidentiality.

119. A question was raised as to what was meant by "public disclosure." It was suggested that the disclosure in a scientific article of the product formula should not be equated with the manufacturing process information and quantitative formula submitted to the Food and Drug Administration. Refinement of a manufacturing process to the point where it produces a drug of high quality is a process more costly and exacting than required to prepare new components which are described in scientific literature.

The Commissioner advises that public disclosure is any lawful disclosure outside of the company and its consultants. Any information that has appeared in a published article has been publicly disclosed. However, such publication constitutes public disclosure only of the information that appears in the article. If only the product formula appears, only the product formula has been disclosed.

120. Questions have been raised as to whether disclosure in litigation is sufficient to break the trade secret status of data and information.

The Commissioner concludes that such disclosure would break the trade secret status of the material unless it were disclosed to the court in camera or pursuant to a protective order or only to defense counsel.

121. Questions were raised in comments as to whether the confidential status of a trade secret will be broken if the information involved has been given to licensees, to Federal or State agencies or foreign governments for regulatory purposes, or to business associates under contract.

The Commissioner advises that, under all the situations described above, the confidentiality of the information will be retained. It is only when the information is given to a member of the public without any arrangement of this type that confidentiality can no longer be claimed.

The Commissioner specifically rejects the suggestion that trade secret material should not lose its confidential status if it is divulged to any member of the public pursuant to any type of "confidentiality agreement." This loose wording would permit, for example a manufacturer to disseminate any information he wishes on a widespread basis, simply through stating in his

letters that receipt of the information constitutes agreement that it will be retained as confidential. The Commissioner concludes that the trade secret laws cannot properly be construed this broadly.

122. A comment asked whether, in a situation where the composition of a new packaging material and process has been published in a patent, but the patent does not reveal the detailed commercial process, the Food and Drug Administration would conclude that the detailed commercial process had been previously disclosed, and thus would release it to the public.

The Commissioner advises that the Food and Drug Administration will find a previous disclosure of information only to the extent that such information has actually been disclosed. In the instance cited in the comment, if the commercial process has not in fact been published in the patent or elsewhere, there has not been prior disclosure and the Food and Drug Administration will not release the information.

123. In one instance during the past 2 years, the Food and Drug Administration denied a consumer's request for release of the identity of a color used in a drug when the company affected informed the agency that it had not previously made this information available to the public. Shortly thereafter, when a physician requested the same information from the company, it was given to him. The Food and Drug Administration then released the information to the consumer who had originally requested it.

The Commissioner concludes that it is important to emphasize to companies who request trade secret status of data or information submitted to the Food and Drug Administration that any statements made with respect to the lack of prior release to the public are subject to the False Reports to Government Act. Accordingly, all communications with firms with respect to this type of issue in the future will contain a statement to that effect.

DISCRETIONARY DISCLOSURE BY THE COMMISSIONER

124. The exemptions for public disclosure under the Freedom of Information Act are discretionary, not mandatory. Numerous occasions have arisen in the past 2 years where the Commissioner has concluded that documents exempt from public disclosure under the Freedom of Information Act should nonetheless be made available to the public. Accordingly, the Commissioner has concluded that new § 4.82 should be added to the final regulations to authorize the discretionary release of documents which could lawfully be held as confidential under the Freedom of Information Act, where the Commissioner concludes that such release would be in the public interest, and where such release is not otherwise prohibited by law.

125. Comments contended that the purpose of the Freedom of Information Act was to make the operations of Federal agencies more available to public scrutiny without subjecting information derived from private sources to unwarranted disclosure. Comments argued that the proposed regulations published in May 1972 released most information supplied by industry without releasing internal Food and Drug Administration memoranda.

The Commissioner advises that the congressional intent was to permit greater public scrutiny of Federal agency operations and the data and information on which those agencies base their decisions. Even though internal agency memoranda are explicitly exempt from disclosure under the law, the final regulations provide for discretionary release of such information whenever the Commissioner concludes it will not hinder agency operations and is in the public interest.

126. Questions have arisen as to whether the Commissioner may, in his discretion, release trade secret information.

The Commissioner advises, for the reasons set out elsewhere in this preamble, that he has no discretion to release trade secret information. All records subject to the trade secrets exemption from the Freedom of Information Act are prohibited from public disclosure pursuant to 18 U.S.C. 1905 and 21 U.S.C. 331(j). These prohibitions are enforceable by criminal sanctions. Accordingly, new § 4.82 does not permit discretionary release of such material.

127. Questions have also arisen with respect to the discretionary release of names of individuals where that would constitute a clearly unwarranted invasion of privacy.

The Commissioner regards the right to privacy as a fundamental principle of law and ethics. Accordingly, new § 4.82 prohibits discretionary release of any information that falls within the personal privacy exemption.

128. Questions have arisen as to whether the written comments of a special government employee sent to the agency with respect to regulations published in the FEDERAL REGISTER will be made public by filing them with the Hearing Clerk of the Food and Drug Administration, along with all other comments on the proposal.

The Commissioner concludes that any such written comments are properly filed with the Hearing Clerk. Similarly, any written comments by other governmental agencies are also properly filed with the Hearing Clerk. The Commissioner concludes that, although these comments could be retained as confidential pursuant to the exemption for inter- and intra-agency memoranda, the policy of developing a full public record for decision on proposed regulations should be paramount. Accordingly, the Commissioner concludes that he will exercise his discretionary authority by placing all such documents on public display in the office of the Hearing Clerk.

129. Concern has been expressed that, if the Commissioner exercises his discretion to release certain types of documents even though they properly fall within an exemption from the Freedom of Information Act, e.g., internal memoranda, this may be regarded as precedent that will require the disclosure of all similar documents in the future.

The Commissioner advises that discretionary release of some documents does not require disclosure of all similar documents. Such a conclusion would be counter-productive, because it would require rigid adherence to the statutory exemptions, and less disclosure of information to the public, contrary to the intent of the Freedom of Information Act. A new provision has been added to § 4.82 of the final regulations to state this policy.

DISCLOSURE PURSUANT TO COURT ORDER

130. Comments pointed out that the Food and Drug Administration cannot guarantee confidentiality for any record, since a court may conclude that the information is subject to public disclosure.

The Commissioner concurs with this comment. Accordingly, new § 4.83 states that a determination of confidentiality by the Food and Drug Administration pursuant to § 4.44, or indeed pursuant to any provision in these final regulations which states that a particular record is exempt from public disclosure, means that the Food and Drug Administration will make the record available for public disclosure only if ordered by a court.

DISCLOSURE TO CONSULTANTS, ADVISORY COMMITTEES, STATE AND LOCAL GOVERNMENT OFFICIALS COMMISSIONED PURSUANT TO 21 U.S.C. 372(a), AND OTHER SPECIAL GOVERNMENT EMPLOYEES

131. Section 4.30 of the proposed regulations published in May 1972, which states that confidential documents may be disclosed to special government employees without disclosing them to all members of the public, is redesignated as § 4.84 in the final regulations.

A comment stated that disclosure to consultants and advisory committees should be made pursuant to a "confidentiality agreement" to insure that the recipients of such information are aware that the data must be treated on a confidential basis.

The Commissioner agrees with this comment. Sections 4.80(c) and 4.84 of the regulations provide that all government employees and special government employees to whom such records are disclosed shall be subject to the same restrictions as Food and Drug Administration employees with respect to their disclosure.

132. In preparing for court cases, the Food and Drug Administration often consults with potential witnesses and, in the course of such discussion, may disclose internal information not previously disclosed to the general public. Questions have arisen as to whether such disclosure triggers the requirement that such information also be made available for public disclosure to any other person who requests it.

The Commissioner concludes that consultation with potential witnesses in preparation for litigation, whether it be in a court or in an administrative hearing, does not fall within the rule that disclosure to one member of the public requires disclosure to all. Although these potential witnesses are not always special government employees, they are government consultants for purposes of the litigation, and thus such consultation falls within the exception established in § 4.64 of the regulations for investigatory records for law enforcement purposes.

133. Comments stated that the Food and Drug Administration should clarify the conditions under which correspondence and summaries of calls and meetings with special government

employees are not disclosable. It was suggested there be disclosure unless the communication relates only and specifically to matters (a) upon which special employees are consulting or advising and (b) which are encompassed within the scope of their duties as special government employees.

The Commissioner agrees with this comment, and § 4.84 has been revised accordingly. To the extent to which a communication by or to a special government employee is not a communication by or to him in that capacity, such a communication is not covered by the inter- or intra-agency memorandum exemption, and is available for disclosure.

134. Questions have arisen with respect to release of data and information to contractors that is exempt from public disclosure.

The Commissioner concludes that since contractors are not special government employees, they stand in the same position as any other member of the public and are not subject to the provisions in § 4.84 of the final regulations.

DISCLOSURE TO OTHER FEDERAL GOVERNMENT DEPARTMENTS AND AGENCIES

135. Questions have arisen about the disclosure of information contained in Food and Drug Administration files to other Federal government departments and agencies.

The Commissioner concludes that all data and information contained in Food and Drug Administration files may properly be disclosed to other Federal government departments and agencies, without regard to the statutory exemptions, or to triggering the necessity for releasing the information to the public generally, except for records subject to the confidentiality provisions contained in section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Thus, for example, preliminary results of scientific testing may be exchanged by government agencies so that they will be kept informed of new developments and can prepare for any appropriate action prior to release to the public of the full results in a final report.

Section 301(j) explicitly provides that the material it covers may only be disclosed within the Department of Health, Education, and Welfare, or to the courts when relevant in any judicial proceeding. This limitation is contained in new § 4.85. Where another Federal government agency has concurrent jurisdiction over a matter, however, and thus also has legal authority to obtain and review material covered by section 301(j), the Food and Drug Administration may share such material directly with that other agency rather than requiring the other agency to obtain it from the original source. This situation occurs, for example, as a result of the joint jurisdiction of the Food and Drug Administration and the Environmental Protection Agency over pesticides that are also new animal drugs.

136. Concern has been expressed that if the Food and Drug Administration makes available to other government agencies information that is exempt from public disclosure, those other agencies may disclose the information contrary to a pledge of confidentiality given by the Food and Drug Administration in writing or in these final regulations.

The Commissioner advises that any data or information furnished to other government agencies that is not disclosable to the general public will be furnished only pursuant to an agreement that the information will be held in confidence. If no such assurance can be given, the data or information will not be furnished. Section 4.85 of the final regulations so provides.

DISCLOSURE IN ADMINISTRATIVE OR COURT PROCEEDINGS

137. No comments were received on the provision in the proposed regulations which stated that data and information exempt from public disclosure may nevertheless be revealed in administrative or court proceedings.

The Commissioner concludes that this provision should be retained in the final regulations under § 4.86. The Food and Drug Administration will, where some disclosure is necessary, take whatever action is reasonable to reduce such disclosure to the minimum necessary under the circumstances.

DISCLOSURE TO CONGRESS

138. The Freedom of Information Act explicitly provides that the exemptions are "not authority to withhold information from Congress" (5 U.S.C. 552(c)).

The rules of Congress provide that the House of Representatives and the Senate act through their committees and subcommittees. Accordingly, a request from Congress for records, i.e., from the chairman of a committee or subcommittee, acting on behalf of that committee or subcommittee, falls within the provision set out in 5 U.S.C. 552(c) and thus is not subject to the exemptions from disclosure. A request for records from an individual member of Congress, on his own behalf or on behalf of any constituent, is subject to all the requirements applicable to a request for records by a member of the public, including the usual exemptions and fees. See "EPA v. Mink," 410 U.S. 73 (1973); "Aspin v. Department of Defense," 491 F.2d 24 (D.C. Cir. 1973). A new § 4.87 has been added to the final regulations to state this policy.

139. A question has arisen as to whether the General Accounting Office is within the provision contained in 5 U.S.C. 552(c) which states that the exemptions from disclosure under the Freedom of Information Act do not apply to "Congress".

The Commissioner concludes that, since GAO was established by an act of Congress with powers to investigate agencies of the executive branch, it is within the exception set out in 5 U.S.C. 552(c) and thus stands on the same footing as congressional committees and subcommittees.

140. Concern has been expressed that information exempt from public disclosure pursuant to the Freedom of Information Act must nonetheless be disclosed to Congress, and that there is no statutory provision prohibiting Congress from disclosing such information. In particular, it has been pointed out that some years ago a congressional committee obtained from the Food and

Drug Administration adverse reaction information which it subsequently published as part of the record of a hearing without deletion of the patient or physician names or other identifying information. As a result, physicians have expressed reluctance to supply such information to the Food and Drug Administration.

The Commissioner concurs that the law presently does not prohibit release by Congress of confidential information obtained from the Food and Drug Administration which is otherwise exempt from public disclosure. However, the Commissioner knows of no instance other than the one mentioned above in which this has happened. In that specific instance, no damage resulted from the disclosure. In discussions with congressional staff members, the Food and Drug Administration has been advised that the single incident mentioned above was an aberration that will be guarded against in the future. The Commissioner therefore concludes that disclosures of this type are extremely unlikely.

COMMUNICATIONS WITH STATE AND LOCAL GOVERNMENT OFFICIALS

141. Section 702(a) of the act (21 U.S.C. 372(a)) authorizes the Food and Drug Administration to commission any health, food, or drug officers or employee of any State, Territory, or political subdivision to act as an officer of the Food and Drug Administration in conducting examinations and investigations for purpose of enforcement of the act. Pursuant to this provision, the Food and Drug Administration has commissioned a number of State and local officials to help enforce the law. In addition, sections 301 and 311 of the Public Health Service Act (42 U.S.C. 241 and 243) encourage cooperative efforts between State and local officials and the Food and Drug Administration in regulatory activities. Indeed, the effectiveness of the Food and Drug Administration is frequently dependent upon the cooperation of such State and local officials.

The Commissioner concludes that all information exchanged between the Food and Drug Administration and a Commissioned State or local official or a State or local official under contract with the Food and Drug Administration to conduct law enforcement work is exempt from disclosure under the Freedom of Information Act pursuant to the intra-agency memoranda and investigatory records exemptions. Such information will be subject to discretionary release by the Commissioner, however, pursuant to the principles established in these new regulations, after consultation with the State or local official involved.

Information supplied to the Food and Drug Administration by a State or local official who is not Commissioned pursuant to section 702(a) of the act, or supplied by the Food and Drug Administration to such a State or local official, presents a somewhat different issue. A large amount of this information consists of investigatory records that are supplied by or to State and local officials on the understanding that they will be retained as confidential and will not be disclosed. The Commissioner concludes that material of this kind obtained by the Food and Drug Administration in accordance with such an understanding with State and local officials will be retained as confidential on the grounds that disclosure would interfere with enforcement proceedings, would disclose the identity of a confidential source, and would disclose investigative techniques and procedures. Similarly, disclosure of information of this type to State or local officials will not require release of the information to the public. The Food and

Drug Administration has no authority to require that State and local officials furnish this information to it. This exchange of information is important to the regulatory activities of the agency. Accordingly, the Commissioner concludes that retention of this information as confidential is fully within the intent of the investigatory records exemption. Similarly trade secrets disclosed to the Food and Drug Administration by a State or local government official will also be retained as confidential.

A new § 4.88 has been added to the regulations to reflect this policy.

COMMUNICATIONS WITH FOREIGN GOVERNMENT OFFICIALS

142. A number of comments raised questions about the status of foreign governments under the proposed regulations. Specific instances have arisen in which a counterpart agency in a foreign country has offered data or information to the Food and Drug Administration on a confidential basis, or the Food and Drug Administration has wished to make data or information available to the foreign government without making it available to the general public at that time. In all instances these matters have related to pending regulatory matters and the communications have represented an attempt to coordinate action on an international level.

The Commissioner notes that there is no specific exemption relating to communications with foreign governments under the Freedom of Information Act, except for classified material relating to national defense or foreign policy. The investigatory records exemption does recognize, however, that documents relating to current regulatory issues may properly be retained as confidential during the period necessary to ensure that enforcement activities are not disrupted. The Commissioner concludes that most, if not all, communications with foreign governments relating to pending regulatory matters properly fall within this exemption. Once the pending action is in fact taken, however, such communications and information would ordinarily become available for public disclosure, except where the foreign nation specifically requires that the information involved be retained as confidential for a longer period of time.

The Commissioner emphasizes the importance of maintaining good working relationships with counterpart agencies throughout the world both to sound diplomatic relations with foreign nations and to the availability of important new information of regulatory significance. Such cooperation is encouraged by sections 301 and 308 of the Public Health Service Act (42 U.S.C. 241 and 242f). Unless regulatory information can be exchanged without required public disclosure, the Food and Drug Administration will lose its sources of important information that is vital to protect the public, and will be unable to disseminate preliminary information when it is first generated within this country in order to help protect the public health throughout the world.

143. A foreign regulatory agency suggested that any information submitted to the Food and Drug Administration by a foreign company, and certified by a foreign government agency as confidential, should be held by the Food and Drug Administration as confidential.

The Commissioner concludes that the same rules with respect to confidentiality apply to foreign companies as to domestic companies under the Freedom of Information Act. An assertion by a

foreign government that information submitted by a foreign company is confidential is insufficient, under the Freedom of Information Act, to require nondisclosure.

144. A comment urged that a special provision be added specifically to retain as confidential any information that is submitted to the Food and Drug Administration by a foreign government in confidence or as trade secret. There was particular concern that confidential information in foreign government inspections reports be automatically treated as confidential. Article 162 of the Swiss Penal Code was cited as subjecting Swiss authorities to a penalty for the disclosure of trade secrets.

The Commissioner advises that the Food and Drug Administration has authority to withhold from disclosure only information specifically exempt from disclosure under the Freedom of Information Act. The Commissioner believes that § 4.89 reflects the current law in this regard and will permit the agency to retain in confidence all trade secret information or investigatory files.

145. Questions have arisen about the status of papers prepared for or by international organizations, particularly the Food and Agriculture Organization and the World Health Organization.

The Commissioner notes that 22 U.S.C. 288a(c) provides that "The archives of international organizations shall be inviolable." The Commissioner interprets this to mean that the United States government and the public may not obtain information directly from such organizations, i.e., the Freedom of Information Act does not apply to such organizations. This does not mean, however, that communications from such organizations to the Food and Drug Administration, or materials prepared by the Food and Drug Administration for such organizations, are not subject to public disclosure under the Freedom of Information Act. The Commissioner concludes that Congress has not granted special immunity to such records. Accordingly, communications to and from such organizations will have the same status as documents to and from any other organization.

146. In particular, a question has been raised about the availability for public disclosure of working papers prepared by an employee of the Food and Drug Administration for the World Health Organization.

The Commissioner notes that when such working papers are prepared by an employee in his capacity as a representative of the Food and Drug Administration, and not in an individual capacity, all such documents are properly available for public disclosure in accordance with the same rules that apply to all records contained in agency files. However, when such records are not prepared during working hours, using the facilities of the Food and Drug Administration, and copies are not included in Food and Drug Administration files, they are not available for public disclosure. Accordingly, the status of such records will be determined by the specific circumstances involved in each instance.

USE OF INFORMATION FOR ADMINISTRATIVE OR COURT ENFORCEMENT ACTION

147. No comments were received on the provisions contained in the proposed regulations stating that any data or information obtained by the Food and Drug Administration, by any ;means whatever, may be used as the basis of taking any appropriate administrative or court enforcement action within its jurisdiction.

The Commissioner concludes that this provision should be retained in the final regulations as § 4.90. *Data and information* that would otherwise be exempt from public disclosure will nonetheless be released in connection with such enforcement action if necessary to implement the specific action involved. For example, the Food and Drug Administration routinely discloses commercial information about recalled products that is relevant to the recall but that would not otherwise be disclosed. The Commissioner concludes that, when enforcement action of this type occurs, such information is customarily revealed and thus the exemption for confidential commercial information is not longer applicable.

AVAILABILITY OF SPECIFIC CATEGORIES OF DOCUMENTS

148. Many of the sections in the proposed regulations published in May 1972 related to the availability of specific categories of documents. Some of these categories of documents are the subject of separate regulations published by the Food and Drug Administration, e.g., food additive petitions and new drug applications, and the detailed rules on the availability of these types of documents are therefore properly incorporated directly into those existing regulations. In many other instances, however, there are no specific regulations dealing with the types of documents involved, e.g., agency correspondence and administrative enforcement records, and therefore separate rules are included in Part 4 to cover these matters.

The Commissioner concludes that a new Subpart F should be established in Part 4 to include all of these provisions relating to specific categories of documents not dealt with elsewhere in Food and Drug Administration regulations. For convenience, a new provision in § 4.100(c) is also included to cross-reference all other sections in the act relating to the availability of documents not specifically dealt with in Subpart F of Part 4.

APPLICABILITY

149. Numerous comments on the proposed regulations published in May 1972 expressed concern that some of the provisions dealing with specific categories of records did not directly incorporate all of the exemptions from disclosure.

The Commissioner advises that each of the exemptions from disclosure set out in Subpart D of Part 4 is applicable to each of the specific categories of records for which a provision is established in Subpart F of Part 4 or elsewhere in Food and Drug Administration regulations. Both §§ 4.60 and 4.100 state this policy.

150. Provisions in other parts of the Food and Drug Administration regulations also establish rules governing the availability for public disclosure of specific categories of records.

For ready reference, new § 4.100(c) lists all of the other Food and Drug Administration regulations relating to public disclosure of records. Additions to this list will be made when the new procedural regulations are published, and when other regulations are published by the Food and Drug Administration setting out rules on the availability of specific records for public disclosure.

ADMINISTRATIVE ENFORCEMENT RECORDS

151. Section 4.21 of the proposed regulations, which made available for public disclosure records of all informal public disclosure records of all informal administrative enforcement action, has been redesignated as § 4.101 in the final regulations.

As with § 1.6(c), a number of comments expressed concern about "trial by newspaper" as a result of release of informal enforcement action records. It was stated that there was a great potential for an imbalanced and distorted view since not all information bearing on the alleged or suspected violation would necessarily be in the files, e.g., information concerning the severity of the violation and the extent of its occurrence. A Food and Drug Administration employee's notes were characterized as subjective and just one individual's opinion. It was suggested that items in a Food and Drug Administration employee's report might be incorrect, and that the company, to protect against such possibilities, should be given the opportunity to review the file and explain it before it is released to the public. It was argued that a rebuttal after the item had hit the newspapers was too late. A denial after disclosure could not repair the damage already done to a business reputation. It was also suggested that, if the agency disclosed warning letters and other requests for corrective action, it should also make public a balanced presentation of the fact, including the fact, if such is the case, that an alleged violation is minor or technical.

The Commissioner concludes that these comments are not persuasive, and that all records of administrative enforcement action disclosed to any person will be made available to the public. If accepted, the logic of the comments summarized above would require holding the pleadings in all court actions confidential until the matter was finally concluded, as well as all administrative actions. The Commissioner concludes that the approach suggested in the comments is in complete disregard of the intent of Congress as expressed in the Freedom of Information Act. See "Wellford v. Hardin," 444 F.2d 21 (4th Cir. 1971).

The Commissioner also concludes that it is not feasible to furnish requested material to an affected person for review, prior to disclosing it to the public, nor is this required by law. Such a procedure would substantially reduce the availability of information to the public contrary to the Freedom of Information Act.

152. Questions have been raised on the difference between "informal" and "formal" enforcement action.

The Commissioner concludes that the term "informal" should be replaced by the term "administrative," in order to clarify the intent of this section. All administrative enforcement action will be governed by this section regardless whether it is considered informal or formal in

nature.

153. Many comments cited the probability of an adverse effect upon a company's desire to cooperate with the Food and Drug Administration if all such correspondence and reports are released to the public. Several stressed the importance of industry cooperation in order for the Food and Drug Administration effectively to regulate the industry. One suggested that the provision might interfere with voluntary compliance, since cooperation might, in the public's eye, indicate guilt. There would be, it was stated, a tendency to resist and litigate rather than to accept "trial by newspaper." It was suggested that manufacturers who previously fully cooperated in an inspection situation would attempt to use section 704 of the Federal Food, Drug, and Cosmetic Act against the Food and Drug Administration employee by questioning the "reasonableness" of inspections and permitting nothing beyond the letter of the law.

The Commissioner concludes, on the basis of experience in the 2 years during which the provision has been implemented, that the fears expressed in the comments are wholly unfounded. There has been no adverse impact upon the cooperation of the regulated industry in complying with Food and Drug Administration requirements.

154. One comment argued that a policy of nondisclosure should apply as much to informal enforcement communications as it does to intra- and interagency communications since industry has the same right as the agency not to "operate in a fishbowl."

The Freedom of Information notes that the Freedom of Information Act specifically exempts intra- and interagency communications. The disclosure of communications between the Food and Drug Administration and industry does not in any way require industry to disclose its own internal decisionmaking process.

155. Questions have been raised about the status of lists of observations left by a Food and Drug Administration employee upon completion of a factory inspection, setting forth observations on violative conditions, pursuant to section 704(b) of the act. These reports are made on Forms FD-483 and, for drugs, FD-2275.

The Commissioner concludes that these are in the nature of warning letters and, since they are provided to the company involved, are also properly provided to any other person who requests them. Even though these reports of observations may form a part of an investigatory file, the Commissioner concludes that their routine release will not interfere with enforcement proceedings or impede a fair trial or an impartial adjudication because there are several thousand of them every year and, unlike section 305 hearing files, they are not closely related to possible criminal prosecution in most cases. Such reports have been released routinely upon request during the past 2 years without prejudice to the agency's regulatory activities.

156. Similar questions have been raised with respect to the status of the establishment inspection report (EIR) prepared by a Food and Drug Administration employee after an inspection. This EIR is retained only in Food and Drug Administration files, and is not sent to the establishment or any other person.

The Commissioner concludes that the EIR is properly retained as confidential until the matter is closed, since it is both an intra-agency memorandum and part of an investigatory file. Unlike the information in Forms FD-483 and FD-2275, the EIR contains personal conclusions and recommendations for consideration only within the Food and Drug Administration, and is not disclosed to anyone outside the agency except other authorized governmental officials. It is not a simple factual list of observations, but a much longer description of conditions observed and conclusions and recommendations with respect to those observations. The Commissioner concludes that routine release of the EIR before the matter is closed would interfere with normal enforcement activities and could have an adverse impact on a fair trial and an impartial adjudication. In specific situations, an EIR may be released by the Commissioner as an exercise of his discretion pursuant to § 4.82.

The list of the Food and Drug Administration employee's observations on violative conditions, given to the responsible company official upon completion of the inspection on Forms FD-483 and FD-2275 contains at least part of the information subsequently incorporated in the EIR. Accordingly, the Commissioner concludes that the Food and Drug Administration will respond to any request for a nondisclosable EIR with an offer to furnish a Form FD-483 or FD-2275 covering the same inspection.

157. In some instances, a Food and Drug Administration employee will discuss matters with a firm during or at the conclusion of the inspection and will subsequently note those and perhaps other matters in the EIR. Questions have arisen as to whether this requires that the EIR be made available for public disclosure.

The Commissioner concludes that an oral discussion of matters subsequently reduced to writing in an EIR does not require that the EIR be made available for public disclosure. If any part of the EIR is subsequently disclosed to the firm or any member of the public, however, the same portion of the EIR must then be made available to anyone who requests it, except for appropriate deletions for exempt material.

158. It is common practice for a representative of the Food and Drug Administration to write a high official in a company to bring to his personal attention any violation of the law that may have been observed during a factory inspection and reported in an EIR.

In accordance with the Commissioner's conclusion that all correspondence with any person outside the Federal government is properly made public, all such postinspection correspondence will be made publicly available upon request. Such letters are in the nature of warnings pursuant to section 306 of the act, and may well be in lieu of seizure. See "Wellford v. Hardin," 444 F.2d 21 (4th Cir. 1971). Such letters have been released publicly for the past 2 years without disruption of the activities of the agency.

159. In many instances, the Food and Drug Administration issues a formal regulatory letter pursuant to section 306 of the act, stating that appropriate court action will be undertaken if specified violations of the act are not corrected.

The Commissioner concludes that all regulatory letters, and all followup correspondence relating to such letters will be made publicly available upon their issuance. These letters constitute administrative enforcement action by the agency and should be subject to the same disclosure principles as court enforcement action.

The Commissioner concludes that a copy of each regulatory letter will be filed in the Food and Drug Administration Public Records and Documents Center, for public review. Additional correspondence and memoranda relating to such letters will be available upon request. Thus, regulatory letters will be handled in the same way as court actions filed by the agency. All regulatory letters issued by the agency during the past 2 years have been made publicly available upon request without any adverse consequences.

160. The Food and Drug Administration often requests the recall of violative products from the market in lieu of seizure.

The Commissioner concludes that all administrative enforcement records requesting recalls are properly released to the public upon request, for the same reasons that regulatory letters and other administrative enforcement records are the subject of public disclosure. The Commissioner believes that all regulatory action taken by the agency, whether of an administrative or of a court nature, must be subject to public scrutiny and public accountability. In releasing records on recalls, however, the Commissioner will delete any confidential commercial information that may be included. For example, a list of customers of a particular company and sales demography data are customarily regarded as confidential commercial information, and will not be disclosed to the public.

161. A number of comments noted the absence in proposed § 4.21 of a specific exemption for trade secret or confidential information and indicated that such an exemption should be added.

As § 4.100(a) makes clear, each exemption from the Freedom of Information Act, including the exemption for trade secret and confidential commercial information, applies to all records released by the agency. The Commissioner concludes that it is impractical to mention each exemption in each section of the regulations.

162. Comments suggested that some of the information covered by this section would also be covered by the section on the investigatory records exemption.

The Commissioner concludes that there is no overlap between these sections. The investigatory records exemption in § 4.64 is explicitly limited only to data and information obtained by the Food and Drug Administration, retained solely in its files, and not shown to anyone outside the agency. Thus § 4.64 covers no communications with an affected person or company, such as the observations left by a Food and Drug Administration employee or product analyses furnished to a company. Section 4.64 covers only the Food and Drug Administration's own investigatory reports which are not made available outside the agency, such as an EIR or any other internal report, as well as information contained in section 305 hearing records and other investigatory

reports relating to an active and current criminal investigation. The provisions of §§ 4.64 and 4.101 have been revised to clarify this policy.

163. A number of requests have been made for "action levels" used by the agency in determining when it will institute administrative or court enforcement action against a product for violation of the law.

The Commissioner advises that all such action levels have, to the best of his knowledge, now been made public. The action levels for natural or unavoidable defects in food are the subject of § 128.10 (21 CFR 128.10). Paragraph 7 of the preamble to the final order promulgating that regulation, published in the FEDERAL REGISTER of January 5, 1973 (38 FR 854), stated that, when finally revised, all such actions levels will be published in the FEDERAL REGISTER for comment, and that in the interim, they would be available upon request from the office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Rm. 15B-42, 5600 Fishers Lane, Rockville, MD 20852. Such action levels are also available at the Food and Drug Administration Public Records and Documents Center.

The Commissioner has recently proposed a revision of Part 122 of the regulations (21 CFR Part 122), published in the FEDERAL REGISTER of December 6, 1974 (39 FR 42738), to provide for publication of all action levels for food products not included within § 128.10. Although the Commissioner recognizes that this project will require a significant amount of resources and cannot be completed in a short period of time, and that legal action can in any event be taken for violation of the law without publication of action levels or enforcement criteria, it is the Commissioner's intent in the future to publish all action levels in the FEDERAL REGISTER with time for comment, in order to codify them in regulations.

In the past, the Food and Drug Administration utilized a "tolerance on a tolerance" under some limited circumstances. In these instances, legal action would not be undertaken against a product which exceeded the announced tolerance or action level but would be taken if it exceeded the unannounced higher tolerance or action level. The legislative history of the Freedom of Information Act shows that such unannounced tolerances may properly be retained by an agency as confidential. Nevertheless, the Food and Drug Administration concluded some years ago that all such unannounced tolerances should be abolished, and none remains in existence today.

A determination that a product violates an action level must, of course, be made on the basis of specified analytical methodology and equipment. In many instances, such methodology yields various results, and thus is accurate only within a specified range. In most instances, this variability is widely known within the scientific profession. The Food and Drug Administration will make available to the public upon request the amount of variation recognized by the agency in considering enforcement action based upon analytical results.

Finally, the Food and Drug Administration has established levels above which its field offices may request legal action directly to the office of the General Counsel, rather than through the Bureau compliance offices. Findings below these levels, but above the action level, must be sent to the Bureau compliance office and then forwarded to the office of the General Counsel. The

Commissioner concludes that these "direct reference levels" need not be held in confidence and may properly be made available for disclosure to the public.

COURT ENFORCEMENT RECORDS

164. The Food and Drug Administration institutes many formal legal actions in the courts every year. These include seizures, injunctions, and criminal prosecutions. The Commissioner concludes that a new § 4.102 should be added to the final regulations concerning the availability of documents relating to these matters.

All legal documents filed in the courts are public information. In order to make certain that accurate copies are obtained, copies of any such documents must be requested directly from the courts involved. The Commissioner concludes, however, that the Food and Drug Administration will make available copies of such documents when it has a copy that can be determined to be in the form actually filed in the court.

165. In some instances, legal actions requested by the Food and Drug Administration are not filed by a United States attorney. Requests have been made for copies of all such records, regardless whether the action was or was not filed.

The Commissioner advises that the correspondence with the United States attorney and the recommended complaints are available for public disclosure upon request in accordance with the provisions of § 4.64 *Investigatory records compiled for law enforcement purposes*. Names of individuals considered for criminal prosecution but not prosecuted will be deleted from such material to prevent an unwarranted invasion of personal privacy and unfair accusations.

CORRESPONDENCE

166. As with §§ 1.6(c) and 4.111, comments suggested that disclosure of all correspondence to the public would seriously affect communications between the Food and Drug Administration and industry because of a reluctance of industry to discuss sensitive issues in a public forum. It was asserted that the public interest would be better served by open communication between the Food and Drug Administration and the regulated industries.

The Commissioner concludes that there is no reason to believe that public disclosure of correspondence would hinder the flow of communications in any way. Experience under this provision during the past 2 years has shown no difficulty whatever. Correspondence between the agency and nongovernmental groups and individuals outside the agency is clearly not exempt under the Freedom of Information Act, except to the extent that portions may fall within the specific exemptions under the law.

167. Comments expressed concern that a specific exemption for trade secrets and confidential commercial information was not included in this provision, since correspondence might well include such information.

The Commissioner advises that the exemption for trade secrets and confidential commercial information applies to all agency records. Any exempt material will be deleted before correspondence is disclosed. Sections 4.60 and 4.100 emphasize that fact.

168. One comment protested that to exempt inter- and intra-agency correspondence, but not correspondence between the agency and industry, was "discrimination" that was "ominous in portent."

The Commissioner advises that the Freedom of Information Act provides for the exemption of inter- and intra-agency correspondence, but does not exempt correspondence between the agency and industry. Any "discrimination" which exists was purposely created by Congress. Moreover, there are persuasive policy reasons for handling these documents in different ways. Internal agency documents reflecting policy deliberations require confidential handling if there is to be a full and frank discussion of all alternatives within the agency. All correspondence with the regulated industries, affected professional groups, Congress, and the public must be disclosed, however, to permit public scrutiny of all the information and views presented to the agency on which a decision is based. Public accountability thus requires a full disclosure of all such materials except where specific exemptions apply and cannot properly be waived, e.g., trade secrets or an invasion of personal privacy.

169. Comments stated that the provision relating to disclosure of correspondence to or from "members of Congress" should be clarified so that it is in accordance with the regulations of the Department of Health, Education, and Welfare which exempts correspondence with Congress from disclosure. Comments suggested that either letters to Congress should be exempted per se or the phrase "members of Congress" might be clarified to indicate that the nonexempt correspondence only includes that correspondence in which a member of Congress is not acting in an official capacity as a member of a duly authorized committee.

The Commissioner concludes that any letters to or from a member of Congress, as well as summaries of oral discussions, regardless of whether the member is acting in an official capacity or as a member of a duly authorized committee, will be available for public disclosure except to the extent that the correspondence contains trade secrets or other nondisclosable information. The final Department regulations adopted this position.

170. Comments stated that confidentiality should be maintained if the correspondence would not have taken place but for an implied assumption or the explicit promise of nondisclosure. The need for an appeal procedure before public disclosure of correspondence was asserted.

The Commissioner has added a new § 4.44 to the regulations to establish a procedure for determining those records which the agency will receive under a determination of confidentiality. Except where such procedure is followed, the Food and Drug Administration will not undertake to retain any information in confidence except specific types of records for which confidentiality is explicitly provided in these regulations, e.g., quantitative formulas that have not previously been made public. Where there is a close question with respect to possible confidentiality, the Commissioner will use the procedure set out in § 4.45 of the final regulations to consult with the

affected person, and that person may then request a court determination on the issue pursuant to § 4.46 if he does not agree with the Commissioner's conclusion.

The Commissioner concludes that these procedural safeguards fully protect the right of the affected person to nondisclosure of confidential information.

171. Comments expressed concern that this provision might be misinterpreted to give the impression that protocols contained in unsuccessful contract proposals are available to the public contrary to the intent of the Department regulations. It was suggested that there were also other types of administrative information which should be free from disclosure, e.g., correspondence with applicants for employment concerning conflict of interest issues, and with private attorneys or national representatives of employee unions concerning grievances, adverse actions, or contract negotiations.

The Commissioner concludes that these comments misinterpreted the proposed regulations. Each of the statutory exemptions reflected in the proposed regulations is applicable to all of the types of records contained in Food and Drug Administration files, including correspondence. Thus, the trade secrets and personal privacy exemptions will be applied wherever the facts in a given situation show that they are applicable. For example, correspondence with a prospective employee concerning conflict of interest issues would be exempt from public disclosure under the personal privacy exemption.

172. Questions have arisen as to whether the general rules with respect to agency correspondence and summaries of telephone calls and meetings will be applicable when the subject of the correspondence or summary is a pending petition or application for approval of a specific ingredient or a product, e.g., a new drug application or a food additive petition.

The Commissioner advises that these general rules will not apply to such correspondence or summaries until the petition or application is approved. Securities analysts, competitors, and many others are interested in the progress of such petitions and applications within the agency. Daily monitoring of such matters by outside individuals or organizations is not contemplated by the Freedom of Information Act. The Commissioner concludes that such correspondence and summaries constitute trade secret and commercial or financial information that is privileged or confidential, until the approval of the ingredient or product is obtained or it is finally disapproved.

Once approval is obtained, or final disapproval results, the Commissioner concludes that all such correspondence and summaries shall be made available for public disclosure except to the extent that specific material may be exempt from disclosure as containing a trade secret or constituting an invasion of personal privacy. Thus, confidential handling will exist only during the deliberative stage of the proceeding, and the agency's decision will be subject to full public scrutiny and public accountability once a decision is final.

Section 4.103 and 4.104 and other specific provisions dealing with petitions and applications have been modified to reflect this policy.

SUMMARIES OF ORAL DISCUSSIONS

173. Comments urged that the agency not totally withhold summaries of telephone calls and meetings if they contain both disclosable and nondisclosable information. It was suggested that the appropriate course in that circumstance would be to delete exempt material and disclose the remainder. Several cases were cited for that proposition, "Gruman Aircraft Engineer Corp. v. Renegotiation Board," 425 F.2d 578 (.D.C. Cir. 1970); "Wellford v. Hardin," 315 F.Supp. 768 (D.D.C. 1970).

The Commissioner agrees with this comment and advises that §§ 4.22 and 4.60 make this policy clear.

174. Comments asked whether the summaries to which this provision applies are intended to be a contemporaneous record or a record prepared in response to a request for information.

As stated in § 4.24 of the final regulations, the Freedom of Information Act does not require the preparation of documents in response to requests for information. Any summary of oral discussions to be disclosed pursuant to § 4.104 will be an existing contemporaneous record. If no such summary exists, none need be prepared. The Commissioner will shortly be issuing comprehensive new procedural regulations that will state the circumstances under which Food and Drug Administration employees will be required to prepare a summary of an oral discussion.

175. One comment advanced the proposition that summaries of telephone calls or meetings relating to a clearly identifiable active file should carry the level of confidentiality of the parent file. Another indicated that confidentiality should be maintained if the disclosure would not have taken place but for an assumption of confidential treatment of the information. Still another drew a parallel between disclosure of the summaries and wiretapping and commented that, since evidence of this nature is not permissible in a court of law, there was a serious question as to whether it should be made available to the public.

The Commissioner concludes that the provisions of the Freedom of Information Act apply only to specific records, not to entire files. Accordingly, it is improper to label any particular file as "confidential" and thus any summary subject to § 4.104 must be reviewed to determine whether, on its own merits, it is disclosable in part or in full.

The Commissioner advises that disclosure of information on the basis of a grant of confidentiality will be subject to the specific procedures set out in new § 4.44 of the final regulations. No other form of confidentiality will be granted except in the form of explicit provisions relating to particular types of documents in the final regulations.

The Commissioner concludes that there is no parallel whatever between preparation and disclosure of a summary of a telephone conversation and wiretapping. The public should be aware that such summaries are routinely maintained. In any event, these regulations and the new procedural regulations constitute public notice that such summaries are being prepared.

176. A number of comments were concerned with the possibility that government-composed summaries of telephone calls and meetings might contain misquotes, inaccurate transcriptions, and one-sided interpretations. It was suggested that the problem of misinterpretation could be dealt with by furnishing a copy of the summary to the nongovernment party. The nongovernment person would then be given an opportunity to reply if inaccuracies existed and any written reply would be included when disclosure was made.

The Commissioner is aware that a summary prepared by one party to an oral discussion is necessarily one-sided. Since all such summaries will be available under the Freedom of Information Act, all persons outside the Federal government who were parties to any such conversation may properly request a copy of the summary in order to verify its contents. The new procedural regulations will explicitly provide that any person outside the Federal government who was a party to such a conversation may himself prepare a summary of that conversation and submit it to the Food and Drug Administration, where it will be retained in the same files as the summary prepared by the Food and Drug Administration. In the event that a request is made under the Freedom of Information Act for any such summary, both summaries (or indeed as many as exist) will be disclosed at the same time pursuant to § 4.104(c).

177. Many comments cited this section as inhibiting frank and open communication between the Food and Drug Administration and industry. One letter suggested, on the strength of "Israel v. Baxter Laboratories," 466 F.2d 272 (D.C. Cir. 1972), that reports of violations by competitors may be the subject of antitrust litigation, and that if under § 4.104 such reports were subject to disclosure it would discourage industry informers.

The Commissioner notes that provisions are included in § 4.64 of the final regulations to protect the confidentiality of information received from informers and confidential sources. Accordingly, the problem raised by this comment will not be encountered. The experience of the Food and Drug Administration under this provision of the past 2 years has demonstrated that disclosure of summaries of telephone conversations and other meetings will not impair the agency's activities.

178. A number of comments referred to the lack of a specific exemption in § 4.24(b) for trade secrets and confidential information and expressed the fear that there would be disclosure without the editing out of such exempt information. Comments noted that confidential information is not per se exempt from disclosure under the Freedom of Information Act. The exemption covers only "commercial or financial information" that is "privileged or confidential." It was argued that the reference to confidential information in this provision was in effect broadening the exemption as it appears in the statute.

The Commissioner concludes that revised §§ 4.60 and 4.100 make it clear that all exemptions provided under the regulations will be applicable to every type of document in the Food and Drug Administration files. The Commissioner agrees that "confidential" information is not per se exempt from disclosure under the Freedom of Information Act, and § 4.61 makes this clear.

TESTING AND RESEARCH CONDUCTED BY OR WITH FUNDS PROVIDED BY THE FOOD AND DRUG ADMINISTRATION

179. Comments asked about the scope of the "nonregulatory testing and research" that would be disclosed under the proposed regulations. It was suggested that the final regulations include a definition of this phrase.

Upon reconsideration, the Commissioner concludes that it is often not feasible to distinguish between regulatory and nonregulatory testing and research, and that, in any event, there is no sound public policy reason for not disclosing both types of testing and research. The intent of the proposal was to retain as confidential the regulatory testing and research that is part of investigatory records for law enforcement purposes. The Commissioner concludes, however, that he should exercise his discretion to release this part of investigatory records upon request in order to make as full a disclosure of agency activities as possible without disrupting enforcement proceedings. All such testing and research would be required to be disclosed in the course of any enforcement proceeding, and thus its earlier disclosure should not have any adverse impact upon agency activities.

Moreover, there are strong public policy reasons for disclosing all regulatory testing and research when it is completed and a final report is available or it is otherwise disclosed to any member of the public. The Food and Drug Administration frequently requests the regulated industry to take appropriate action based upon the results of such testing and research, such as recalls. It would be unfair to request such industry action without at the same time disclosing the basis for the request.

180. The proposed regulation provided that a list of nonregulatory testing and research being conducted by or with funds provided by the Food and Drug Administration, together with any research contract, would be available for public disclosure.

In seeking to implement this proposed provision, the Commissioner has discovered that, as already noted, it is not feasible to divide testing and research into regulatory and nonregulatory purposes nor is it practical to maintain a current list of all testing research being conducted by the agency. All research contracts are of course available for public disclosure, and any internal list of ongoing testing or research is also available upon request.

The Commissioner therefore concludes that § 4.105(a) should be revised to delete the requirement for preparation and maintenance of a comprehensive list of all agency testing and research, but to retain the provision stating that any list of agency testing and research that is prepared will be available upon request.

181. Comments requested clarification of the term "final report." If some form of agency approval is necessary before the results of such research can be characterized as "final," the public should be informed whether or not this would mean an effective agency method for preventing disclosure of testing and research the agency deems ill-advised to release, i.e., by simply never characterizing a report as "final." The comments cited "Consumers Union v.

Veterans Administration," 301 F.Supp. 796 (S.D.N.Y. 1969), in which the court ordered the Veterans Administration to release raw test data on hearing aids, for the proposition that raw data in a tabular form must be released.

The Commissioner concludes that, until a report is completed and accepted by the responsible Food and Drug Administration official, it represents an intra-agency document that is not available for public disclosure. The Freedom of Information Act does not require premature disclosure of internal agency information before it is in final form, but was intended to promote disclosure of such internal agency information after it is put in final form. Release of tentative data, preliminary reports, or similar material would seriously hinder regulatory efforts of the agency.

The Commissioner fully concurs that any attempt to retain internal data and information as incomplete or, in any event, not "final" for any significant period of time is properly regarded as a violation of the intent of the Freedom of Information Act and will not be tolerated. The provisions of § 4.105 must not be used to avoid disclosure of embarrassing material or information that may cause public concern. Rather, this section is intended to permit the agency time to prepare a responsible final report that reflects an institutional approach to the matter, and a reasonable time for review of the report internally in order to determine any appropriate action before it is released to the public.

The case of "Consumers Union v. Veterans Administration" does not justify a contrary result. There, the data involved were included in a final report and were not simply worksheets or preliminary drafts from which a final report had not yet been prepared. Moreover, the reports involved in that case had been available for a sufficient period of time to permit internal review and consideration, and no reasonable basis for failing to disclose them to the public was offered.

182. Questions have been raised as to the availability of the raw data and slides from Food and Drug Administration studies once they are completed and a final report is released.

The Commissioner advises that access to all raw data, slides, worksheets, and other similar working materials will be granted, once a final report is available.

183. Comments suggested that the statement in paragraph 4 of the preamble of the proposal to the effect that the results of testing and research represent internal information, should be clarified. The application of the internal memorandum exemption to such records was questioned.

The Commissioner concludes that the internal memorandum exemption under the Freedom of Information Act covers only the preliminary results of testing and research and draft reports based upon testing and research prior to acceptance of a final report. Once a final report is prepared, the internal memorandum exemption is not applicable to that report and it, together with any raw data, is available for public disclosure. Any draft reports remain exempt from public disclosure after the final report is released.

184. Questions have been raised as to whether preliminary data obtained from agency testing or research is disclosable if it forms the basis for a talk or other public presentation prior to preparation of a final report.

The Commissioner advises that, once such information is disclosed publicly by the Food and Drug Administration in any way, whether in correspondence or in a private conversation or in a public talk, all of such information reasonably related to the material disclosed must be made publicly available at that time even though a final report has not yet been prepared. Authorized dissemination of any data or information to persons other than as provided in Subpart E of Part 4 breaks the internal memorandum exemption and requires disclosure of such data or information to any person who requests it.

185. One comment expressed uncertainty as to whether testing done on marketed drugs would be disclosed to the public. If so, it was argued that the manufacturer should be given the opportunity to review the results and comment upon them before the report was made available to the public. Another comment suggested that a summary of the research should be prepared so that the study might be properly understood by the lay public.

The Commissioner concludes that all testing on marketed drugs, whether for regulatory or nonregulatory purposes, will be available for public disclosure. Comment by the manufacturer before the release of test results is not feasible or required by the law. The preparation of summaries of this research, as suggested, is not contemplated by the Freedom of Information Act and the agency cannot justify the expenditure of manpower which would be required to create such documents.

186. The Food and Drug Administration obtains two different types of product samples in the course of its regulatory activities. A Food and Drug Administration employee will often obtain a sample during a factory inspection. The Food and Drug Administration employee must give a receipt for such a sample, and a copy of the results of certain analyses are required by law to be furnished promptly to the person from whom the sample was obtained. Where a sample is obtained other than through a factory inspection, and it results in a seizure, the Food and Drug Administration is required under section 304(c) of the act to furnish the results of any analysis to any party to the seizure action. There is no legal requirement that the Food and Drug Administration furnish the results of any other analyses to any person who might be affected by them.

The Commissioner concludes that, regardless of the origin of any sample obtained by the Food and Drug Administration, the results of any analysis of a sample will be made available upon request to any interested person, whether or not that person is directly affected by the results of the analysis. As a matter of policy, any affected person should immediately be given the results upon request in order to take appropriate action. In accordance with the general principle that any information available to one member of the public must be available to everyone, the Commissioner concludes that all analyses of this type should be made generally available to the public upon request.

187. Several comments noted the possibility that agency research might rely, in part, on manufacturer-generated trade secrets or confidential commercial information. It was stated that this provision of the regulations should deal explicitly with this possibility and should exempt from disclosure any trade secret or confidential information utilized in such studies which had been supplied by nongovernment sources.

The Commissioner advises that § 4.61 of the regulations applies to disclosure of trade secrets and confidential commercial information in any agency documents, and §§ 4.60 and 4.100 of the final regulations make this clear. The Commissioner concurs that trade secret information may not be disclosed. This does not mean, however, that agency research or regulatory requirements cannot be based upon trade secret information. For example, bioavailability data on a drug submitted by a manufacturer may constitute trade secret information that is not disclosable to the public. This trade secret status of the underlying information would not prevent the Food and Drug Administration from conducting and disclosing its own similar research, however, or from imposing by regulation new requirements for the drug involved in order to protect the public health.

188. A comment pointed out that, in its performance tests and analyses, the Food and Drug Administration may include trade secrets or other confidential commercial data in test protocols or records of the testing.

The Commissioner advises that any trade secrets or confidential information involved in testing or research will be deleted before the results are made available for public disclosure.

STUDIES AND REPORTS PREPARED BY OR WITH FUNDS PROVIDED BY THE FOOD AND DRUG ADMINISTRATION

189. Questions have arisen as to what internal Food and Drug Administration reports and studies are available for public disclosure.

The Commissioner has reviewed the various categories of reports and studies conducted by the Food and Drug Administration, and has set out in new § 4.106 those types that will be disclosed and those that will be retained as confidential under the internal memorandum exemption. The Commissioner recognizes that a number of these reports may be partially or fully exempt under the internal memorandum exemption, but has concluded that it is in the public interest to release as many of them as feasible when they are prepared in final form. In general, the following types of reports and studies will be disclosed upon their acceptance by the responsible agency official: Quarterly and annual reports of the agency; broad reviews of agency needs by external committees, such as the Ritts Committee; surveys, compilations, and summaries of industry trends and data obtained from various outside sources for purposes of establishing internal priorities and programs; surveys of consumers or industry and other similar studies undertaken to determine the need for or content of proposed new regulations or compliance programs; and compliance studies undertaken to determine the performance of the regulated industry or the products it produces, such as contamination of foods or the sanitation status of a particular type of food plant. As a general rule, the following types of studies will not ordinarily be disclosed to

the public: Internal audits of agency performance to determine the possible need for personnel changes or other action to strengthen agency performance; the records relating to the internal planning and budget process; and legislative proposals or comments unless and until they are submitted to Congress.

190. In particular, questions have been raised about the availability of the results of special drug surveys, and FORDS studies (Formulator Oriented Rx Drug Study).

The Commissioner advises that all such analyses and surveys are available for public disclosure without deletion of the brand name or lot number involved. The Bureau of Drugs of the Food and Drug Administration presently publishes the results of such analyses and surveys on a periodic basis.

191. Questions have been raised about the public availability of Food and Drug Administration compliance programs, which are sent to field offices to direct specific regulatory activities.

The Commissioner advises that all such compliance programs are available for public disclosure upon request, with any names of specific firms, the location of specific activity, and details about sampling numbers or sizes deleted in order to preclude disclosure of regulatory activities.

192. Questions have been raised about the availability of final agency work plans prepared by bureaus, field offices, and other agency components, as well as the yearly and other agency plans prepared by the office of the Commissioner for the entire agency.

The Commissioner advises that all such plans are available for public disclosure after they have been reviewed and approved by the responsible agency official in their final form, with any information about specific regulatory activities deleted.

FOOD AND DRUG ADMINISTRATION MANUALS

193. Questions have arisen about the status of various manuals maintained by the Food and Drug Administration, such as the Regulatory Procedures Manual, the Administrative Guidelines Manual, and similar material.

The Commissioner advises that all such manuals have been reviewed to delete confidential internal directives, and are available for public review in the Food and Drug Administration Public Records and Documents Center. Copies of these manuals may also be purchased at cost, but the Food and Drug Administration does not maintain a mailing list for amendments to these manuals because of the prohibitive expenses involved. A complete index of all such manuals is being prepared and will be available from the Food and Drug Administration Public Records and Documents Center pursuant to § 4.26. A partial list of these manuals is as follows:

Administrative Guidelines Manual
Bacteriological Analytical Manual
Drug Autoanalysis Manual

Food Additives Manual
Inspector Operations Manual
Inspector Programs Manual
Instrument Operations Manual
Laboratory Information Bulletins
Laboratory Operations Manual
Microanalytical Manual
Pesticide Analytical Manual
Regulatory Procedures Manual

194. A comment contended that all agency operating manuals must be made available under the Freedom of Information Act, and that the exemptions from disclosure do not apply to any portion of them.

The Commissioner disagrees with this comment. Nothing in the legislative history of the Freedom of Information Act indicates that otherwise nondisclosable information must be made available through agency operating manuals. Accordingly, the Commissioner has reviewed all such manuals and deleted from them information that falls within any of the exemptions from disclosure. All of those manuals, as so revised, are now available for public review and purchase.

AGREEMENTS BETWEEN THE FOOD AND DRUG ADMINISTRATION AND OTHER DEPARTMENTS, AGENCIES, AND ORGANIZATIONS

195. Requests have been made for copies of agreements entered into by the Food and Drug Administration with State and Federal agencies and with private organizations.

The Commissioner has recently issued a notice, published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697), stating that all such agreements are on file in the office of the Food and Drug Administration Public Records and Documents Center, and that all future agreements will be published in the FEDERAL REGISTER. A new § 4.108 has been added to state this policy.

DATA AND INFORMATION OBTAINED BY CONTRACT

196. Various questions have been raised about the availability for public disclosure of data and information furnished to the Food and Drug Administration pursuant to contracts with outside organizations. In particular, the question has been raised whether information can be purchased by the Food and Drug Administration by contract, with a clause which precludes public dissemination. Some private organizations, for example, undertake market research surveys and then sell the results to purchasers who must agree not to distribute the information further. This type of contract is used so that one person to whom the reports are sold will not furnish them to a second person. There has been concern that the Freedom of Information Act would preclude the Food and Drug Administration from purchasing such information pursuant to a contract of this type.

The Commissioner concludes that the Freedom of Information Act does not permit the Food and Drug Administration to purchase information under a contract that prohibits its further public distribution, unless the information is otherwise exempt from disclosure. All information obtained by the Food and Drug Administration through a contract is available for public disclosure unless it falls within a specific exemption established in Subpart D of Part 4 of the regulations.

The Commissioner notes that, on occasion, the Food and Drug Administration has also entered into contracts which permit representatives of the agency to review data and information retained by an outside organization. Such contracts permit access to outside data and information, but do not permit the Food and Drug Administration to obtain copies of such material. Under these circumstances, since the Food and Drug Administration does not have copies of the documents in its files, the Freedom of Information Act is inapplicable.

197. A question has arisen as to whether the progress reports on contracts, which are usually submitted to the Food and Drug Administration quarterly, are available for public disclosure.

The Commissioner advises that the Freedom of Information Act requires that all information received under contract, including progress reports, is available for public disclosure when received by the Food and Drug Administration, except to the extent that it contains material otherwise exempt from public disclosure under these regulations.

INFORMATION ABOUT FOOD AND DRUG ADMINISTRATION EMPLOYEES

198. Questions have arisen as to what information is available about Food and Drug Administration employees.

The Commissioner advises that the name, title, grade, position description, salary, and work address and telephone number for every Food and Drug Administration employee is available for public disclosure. The home address and telephone number of such employees are not available because they fall within the personal privacy exemption. A new § 4.110 has been added to the regulations to state this policy.

199. The Food and Drug Administration has received a number of requests with respect to prior employment experience of present agency employees, and present employment of past agency employees. Although no such lists had been kept in the past, the Commissioner concluded that research should be undertaken in order to respond adequately to inquiries of this type.

The Commissioner advises that the statistics obtained from this research are available for public disclosure at the Food and Drug Administration Public Records and Documents Center. They will be kept up to date on a periodic basis. Pursuant to the exemption for personal privacy, the raw data are not available for public disclosure.

DATA AND INFORMATION SUBMITTED VOLUNTARILY TO THE FOOD AND DRUG

ADMINISTRATION

200. Section 4.26 of the proposed regulations published in May 1972, dealing with data and information submitted voluntarily, has been redesignated as § 4.111 in the final regulations.

Several comments objected to the concept of permitting information to be withheld as confidential simply because the manufacturer would refuse to submit it unless it was so held. It was argued that the Freedom of Information Act makes no such distinction and that such an approach flouts the express intention of Congress to entitle all citizens to information in the hands of the agency which is not specifically exempt under the Freedom of Information Act.

The Commissioner agrees that a mere claim for confidential treatment does not bestow a confidential status upon information that is voluntarily submitted. Section 4.111 reflects the necessity for showing that the information falls within one of the exemptions set out in Subpart D of Part 4 of the regulations. A claim of nondisclosure based upon the trade secrets or confidential commercial information exemption or any other exemption to the Freedom of Information Act will not be automatically accepted. When the Food and Drug Administration makes a determination that information will be accepted in confidence, the agency is at the time exercising its judgment that the information properly falls within an exemption from disclosure and that the Commissioner will not exercise his discretion to disclose it pursuant to § 4.82.

201. The Food and Drug Administration has instituted a system of inspection of the food industry on the basis of hazard analysis and critical control points (HACCP). Food and Drug Administration employees regularly request, pursuant to this program, access to company records that are not required by law at this time to be given to the Food and Drug Administration for review and evaluation. Numerous questions have arisen about the availability of such records under the Freedom of Information Act after they become a part of Food and Drug Administration files.

The Commissioner advises that such records fall within the provisions in the final regulations relating to information voluntarily submitted to the government, except for those records required to be submitted by other provisions, e.g., § 90.20. Virtually all such records consist of information relating to manufacturing processes and controls, product formulations, and consumer complaints. Manufacturing processes and controls and product formulations are per se exempt from disclosure under the Freedom of Information Act, except to the extent that they have already been publicly disclosed. Consumer complaints are exempt from disclosure to the extent set out in § 4.111(c)(3)(v) of the final regulations, i.e., they will be released only as part of a blind compilation.

202. Comments contended that information given voluntarily to a Food and Drug Administration employee during a factory inspection should be considered confidential unless the employee obtains the signature of a company representative permitting him to make the information public.

The Commissioner concludes that information given by a company representative voluntarily to

the Food and Drug Administration during a factory inspection will be governed by the rules set out in § 4.111 of the final regulations, and § 4.111(a) so provides. No special rules need be established for information given voluntarily during a factory inspection as contrasted with any other time.

203. Comments contended that the Food and Drug Administration should not distinguish between information submitted voluntarily and involuntarily, and suggested that the agency should reject all "voluntary" information in order to impress upon Congress the need for new legislation to compel submission of such data and information.

The Commissioner rejects this comment. As the agency designated by Congress to protect against distribution of adulterated or misbranded food, drugs, cosmetics, devices, and electronic products, the Food and Drug Administration is obligated to obtain all data and information, from any source, that will assist it in these important regulatory efforts. The Food and Drug Administration will also continue to request appropriate legislation from Congress to provide important new investigatory and enforcement tools.

204. Questions have arisen about the status of reports of adverse reactions to products, where such reactions are submitted voluntarily by the manufacturer, i.e, not pursuant to the requirements of the new drug or prescription drug factory inspection sections of the law or pursuant to a procurement contract. The law presently does not authorize the Food and Drug Administration to require that reports of such adverse reactions be furnished to it.

The Commissioner advises that such adverse reaction reports are subject to the following disclosure rules, depending upon the source of the information and any request for confidentiality submitted with it. If the reaction is reported in a consumer complaint letter, it will be made public after deletion of any information that would identify the individual involved. If it is made by a physician or other health professional, it will be made public after all identifying information relating to the patient, physician, and institution has been deleted, but the identification of the product will be released. If the reaction is reported by a manufacturer, public disclosure of the report will be made only in the form of a compilation of all adverse reaction reports, in a way that will not relate to a specific brand name or manufacturer, except when regulatory action is involved, e.g., a product recall. The Commissioner concludes that the personal privacy and confidential commercial information exemptions justify these rules.

205. Experience during the past 2 years has shown that manufacturers and physicians are uniformly unwilling to divulge consumer complaint or adverse reaction information, or other materials of this type, voluntarily except on a pledge of confidentiality.

Accordingly, the Commissioner concludes that it serves no useful purpose to require, in every instance of voluntary disclosure of this type, that the manufacturer or physician be requested to state whether the information will be disclosed without such a pledge of confidentiality. Adherence to such a provision would simply increase administrative red tape and serve no public interest. Section 4.111(c)(3)(ii) and (iii) of the final regulations therefore provides for appropriate deletions of information where it is provided by a physician, and provides that

reports submitted by a manufacturer may be released only as part of a blind compilation that will not reveal the name of the manufacturer or the brand name of the product involved except when regulatory action is involved.

206. The Food and Drug Administration has established a medically oriented data systems (MODS) program under which it enters into contracts with hospitals and other medical institutions for reporting to the agency, upon the payment of a standard fee, adverse reactions and other medical information related to projects subject to the agency's jurisdiction.

The Commissioner advises that the reports obtained pursuant to such contracts are not submitted voluntarily, and thus are subject to § 4.109, which establishes the disclosure rules for information obtained by contract. Pursuant to § 4.63 the name or other information which would identify patients will be deleted prior to disclosure of such reports, but the identity of the reporting institution will be disclosed. The name of any physician or other health professional will also be disclosed if any such name is included in the report, but the contracts involved do not require the reporting of any such names.

207. One comment suggested that the provisions which permit names of those submitting adverse reaction data to remain confidential "applauds the sniper" and that if an individual is unwilling to be identified he should not be heard to complain.

The Commissioner concludes that there are valid reasons why an individual might wish to submit information in confidence. It should be noted that if an individual is not identified and the complaint cannot be followed up, this may affect the weight accorded the complaint by those to whom it is disclosed.

208. Comments contended that the Freedom of Information Act does not allow the Food and Drug Administration to distinguish between the handling of adverse reactions to products for which reports must be submitted to the agency, and adverse reactions to products for which the agency presently cannot require such reports.

The Commissioner disagrees with this comment. Until new legislation is enacted authorizing the Food and Drug Administration to obtain adverse reaction reports from manufacturers on all products subject to its jurisdiction, the agency is dependent upon the voluntary submission of such information for all products except new drugs and prescription drugs. Adverse reaction information is often of critical importance in determining the safety, or lack thereof, of a marketed product. Without such information, the Food and Drug Administration's efforts to prevent the continued marketing of an unsafe product would be substantially hindered.

Nothing in the legislative history of the Freedom of Information Act indicates that this law was intended to be applied in a way that would hinder regulatory activity or prevent an agency from taking action to protect the public health. The Commissioner believes that it is entirely reasonable to conclude that adverse reaction reports that are not required to be submitted to the Food and Drug Administration, and which the manufacturer will not otherwise submit, fall within the exemptions for confidential commercial information, personal privacy, and

investigatory records. Accordingly, the Commissioner has pledged the confidentiality of such reports as provided in § 4.111(c)(3)(ii) in order to assure that they will continue to be available to the agency for its regulatory purposes.

The Commissioner recognizes the anomaly created by classifying certain portions of adverse reaction reports not required by law to be submitted to the government as confidential, while at the same time classifying those same portions of other adverse reaction reports that are required by law to be submitted to the government as not confidential. The Commissioner concludes that this anomaly must continue to exist as long as the disparity in legal authority survives. The alternative would be to discourage voluntary submission by manufacturers of any adverse reaction reports not required by law. The Commissioner concludes that this alternative would not be in the public interest.

209. Comments suggested that adverse reactions should be disclosed by the Food and Drug Administration only to health professionals, and not to the general public, in order to avoid false alarm and damage to the public health.

The Commissioner concludes that limited distribution of this type is precluded by the Freedom of Information Act, and is not in the public interest.

210. Comments suggested that reports of adverse reactions submitted to the Food and Drug Administration by someone other than the manufacturer should be available for public disclosure only after probable causation has been studied and documented and the manufacturer of the product involved has had an opportunity to comment with respect to the alleged reaction.

The Commissioner disagrees with this comment. The Freedom of Information Act nowhere provides for a procedure of this type, which would severely hinder the dissemination of information that is clearly available for public disclosure under the Freedom of Information Act.

211. Comments contended that many consumer complaints are not based on fact, but are simply intended to obtain refunds on products or are, in any event, based upon mistaken impressions. It was contended that it would be unfair to reveal all such complaints because of the many inaccuracies they contain.

The Commissioner recognizes that both industry and consumer versions of complaints may be inaccurate. This is not a basis for exempting reports on complaints or adverse reactions from disclosure under the Freedom of Information Act.

212. Large numbers of requests are received from plaintiffs' attorneys in product liability lawsuits, requesting records relating to any other injuries caused by the product that is the subject of the lawsuit.

The Commissioner advises that, in response to such requests, all such adverse reaction reports received on the product involved will be furnished, with identifying information deleted as provided in § 4.111(c)(3), except that those reports submitted voluntarily by the manufacturer to

the Food and Drug Administration will not be released in any form other than as part of a blind compilation. Section 4.111 of the final regulations reflects this policy.

213. Numerous requests are made for copies of investigations conducted by the Food and Drug Administration of specific consumer complaints.

The Commissioner concludes that such complaints fall within the rules for disclosure set out above. Accordingly, they will be released depending upon the source of the information that led to the investigation. The original consumer complaint that initiated an investigation will be released after deletion of the person's identity. No disclosure of the Food and Drug Administration report shall be made if it relates to a specific person or event without the express written consent of the person who was the original source of the information that resulted in the investigation, since otherwise it would not be possible to promise that such information will be held in confidence.

VOLUNTARY DRUG EXPERIENCE REPORTS SUBMITTED BY PHYSICIANS AND HOSPITALS

214. The Food and Drug Administration has given wide distribution of Form FD-1639, Drug Experience Report, to physicians for use in reporting adverse reactions relating to drug products to the Food and Drug Administration. This form is stamped "In confidence," and the Food and Drug Administration has pledged that no information on this form that would identify patients or physicians or institutions will be released to the public.

The Commissioner advises that this commitment will in all instances be honored under the personal privacy, confidential commercial information, and investigatory records exemptions, and that any release of information contained on this form will be through a compilation that will in no way disclose the identity of any individual patient, physician, or institution. A new § 4.112 has been added to the final regulations to state this policy.

215. Questions have arisen as to whether a copy of the Form FD-1639, with all identifying information deleted, will be made available to the patient who is the subject of the report, or his attorney, if it is specifically requested.

The Commissioner concludes that no release of this report may be made to a patient or his representative without the permission, in writing, of the physicians who submitted the report. If the report were disclosed to the patient, for purposes of malpractice litigation, this entire voluntary reporting system could be destroyed. The Commissioner concludes that, since all of the information contained in any such report can be obtained from the physician through discovery in the course of litigation, the patient has an equally effective alternative.

VOLUNTARY PRODUCT DEFECT REPORTS

216. The Food and Drug Administration has entered into a program with the United States Pharmacopeia (U.S.P.) under which reports on drug product defects are furnished to the agency

for use in determining whether regulatory action is warranted. Under this program, the Food and Drug Administration has pledged that the names and identifying characteristics of physicians, patients, pharmacists, institutions, and similar persons will be deleted prior to public disclosure of any report. Similar programs are being pursued with other organizations.

The Commissioner advises that all commitments with respect to confidentiality of identifying information of this type will be honored, under the personal privacy, confidential commercial information, and investigatory records exemptions. A new § 4.113 has been added to the final regulations to state this policy.

217. A request was received for a compilation of all the drug defect reports received for one particular drug pursuant to the joint program undertaken by the United States Pharmacopeia and the Food and Drug Administration.

The Commissioner advises that specific reports will be disclosed after deletion of information that would identify any individual. A compilation of reports showing the number of reports for each drug, by generic name or by brand name, is also available for public disclosure.

The Commissioner realizes that the Food and Drug Administration does not necessarily investigate each defect report, and therefore their accuracy cannot be verified. Where this is the situation, release of such reports may be accompanied by an explanatory statement to that effect.

DATA AND INFORMATION SUBMITTED PURSUANT TO COOPERATIVE QUALITY ASSURANCE AGREEMENTS

218. The Food and Drug Administration has entered into a number of cooperative quality assurance agreements with members of the food industry. These agreements provide that the company will disclose to the Food and Drug Administration pertinent internal records and documents which are not required by law to be disclosed, and which the company regards as confidential trade secret and commercial information.

The Commissioner advises that all records and documents of this nature which are voluntarily disclosed pursuant to a cooperative quality assurance agreement will be retained by the Food and Drug Administration as confidential in accordance with § 4.111. In order to clarify this matter, a new § 4.114 has been added to the regulations to state this policy.

219. Questions have been raised at to whether the Better Salmon Control Plan entered into between the National Canners Association and the Food and Drug Administration, and any records obtained from companies pursuant to this plan, will be available for public disclosure under the Freedom of Information Act.

The Commissioner advises that the plan is available for public review in the office of the Food and Drug Administration Public Records and Documents Center. All company records obtained pursuant to the plan will be handled in accordance with the rules set out in §§ 4.111 and 4.114 of these final regulations for information voluntarily submitted to the Food and Drug

Administration relating to quality assurance. No records relating to manufacturing procedures and quality control will be available for public disclosure.

PRODUCT CODES FOR MANUFACTURING OR SALES DATA

220. Requests have been made for the keys to the codes used by manufacturers to identify the actual date of manufacture of an electronic product subject to regulation under the Radiation Control for Health and Safety Act of 1968.

The Commissioner advises that the keys to all such codes have been made available for public disclosure. Final regulations revising 21 CFR 1002.10(b) and 1010.3(a)(2) were published in the FEDERAL REGISTER of May 8, 1974 (39 FR 16227), requiring that, in the future, the date of actual manufacture must be stated on the product in understandable terms rather than in code.

The Commissioner concludes that coded information with respect to a date of manufacture, a date by which the product should be sold, or a date by which the product should be used, do not fall within the trade secrets or confidential commercial information exemption. Accordingly, any key to such a code in Food and Drug Administration files will be available for public disclosure. A new § 4.115 has been added to the final regulations to state this policy.

DRUG LISTING INFORMATION

221. The Drug Listing Act of 1972 (Public Law 92-387, 86 Stat. 559), which amended section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), requires drug manufacturers to submit specific information to the Food and Drug Administration with respect to marketed drugs. This provision of the law contains its own confidentiality requirements, and there is extensive legislative history interpreting them.

The Commissioner has previously promulgated regulations in the FEDERAL REGISTER of March 7, 1973 (38 FR 6258), establishing Part 132 of the regulations (21 CFR Part 132) implementing these provisions of the law. All requests for information obtained by the Food and Drug Administration pursuant to section 510 of the act will be handled in accordance with the provisions of Part 132. Accordingly, new § 4.116 cross-references the confidentiality provisions of these regulations.

NEW DRUG INFORMATION

222. The Food and Drug Administration Bureau of Drugs has computerized a large amount of information relating to investigational new drug notices and new drug applications, extending back to the enactment of the Federal Food, Drug, and Cosmetic Act in 1938. Questions have arisen as to what information will be made available for public disclosure, and in what form, from this computer bank of information.

The Commissioner concludes that certain basic information on previously approved new drug applications should be readily available to any member of the public who wishes to review it,

without costs. Accordingly, the following two computer printouts have been placed on public display in the office of the Food and Drug Administration Public Records and Documents Center, where they may be reviewed during working hours:

a. A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and where applicable, the date approval was withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

b. A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved. This printout shows the same information as the first printout, except that it does not show a withdrawal date.

Copies of these printouts may be ordered, at cost. Orders will be filled in accordance with the priorities established for use of the Food and Drug Administration computer.

In addition to the two computer printouts that will be permanently available for public review, the following examples of information may be obtained in printout form upon special request:

a. An alphabetical list by trade name of the approved new drug applications and abbreviated new drug applications held by specific applicants.

b. An alphabetical list of the trade names of drugs subject to approved new drug applications and abbreviated new drug applications showing either the NDA number or the applicant or both.

c. An alphabetical list of generic drugs showing approved new drug applications and abbreviated new drug applications held by applicants.

d. An alphabetical list of commercial sponsors who have filed investigational new drug notices.

Orders for such printouts will also be filled as rapidly as possible, and subject to other priorities for the Food and Drug Administration computer.

The Commissioner concludes that a list of all drugs subject to investigational new drug notices constitutes trade secret information that may not be disclosed to the public.

223. The Food and Drug Administration has received requests for a list of the names and addresses of all investigators who have ever worked on investigational new drugs, without designating the specific drugs they investigated. A similar request has been received for a list of the names and addresses of all drug companies or sponsors who have ever filed an investigational new drug notice (IND) or a new drug application (NDA), without designating the specific drugs involved.

The Commissioner advises that such lists are available for public disclosure to the extent that they already exist in documentary form or can be obtained from computer printouts by existing

programs.

ADVISORY COMMITTEES

224. One comment contended that the provision in the proposed regulations relating to advisory committees "perpetuates the secrecy that has characterized the deliberations of FDA advisory committees" and proposed that the following items be required and available for disclosure:

a. The transcript of each advisory committee meeting where the same had been stenographically reported, or a complete summary of the proceedings, if not stenographically reported. The transcript or summary shall contain a record of the persons present with their affiliations, a description of the matters discussed and the conclusions reached, and copies of reports and background information received, issued, or approved by the advisory committee. The accuracy of a summary shall be certified by the chairman of the advisory committee. Participants shall be given an opportunity to review and make corrections before a summary is certified.

b. A complete and accurate summary of each meeting or telephone call that relates, in whole or in part, to advisory committee business which was conducted at a time or place not covered by reasonable notice in the FEDERAL REGISTER as a time or place for a meeting of the advisory committee. This provision governs whether the meeting or telephone conversation involved advisory committeemen only or advisory committeemen and strangers. In case a stranger is involved, his affiliations will be disclosed.

c. A copy of each directive or guideline given to the advisory committee by the Food and Drug Administration.

d. A copy of the agenda of each meeting of an advisory committee.

e. A list of the names of all the corporations, companies, firms, state or local organizations, research organizations, and educational or other institutions in which an advisory committeeman is serving as an employee, officer, member, owner, director, trustee, advisor or consultant.

f. A list of persons who were asked to become advisory committeemen and who declined. The reason for declining, if any were given will be disclosed.

The Commissioner will issue in the near future comprehensive new procedural regulations in 21 CFR Part 2 that will include provisions governing all aspects of the activities of advisory committees. The Commissioner concludes that detailed consideration of the application of the Freedom of Information Act to advisory committee matters should properly be dealt with in those regulations, rather than these regulations, and an appropriate cross-reference is included in § 4.118 for this purpose.

COLOR ADDITIVE, FOOD ADDITIVE, ANTIBIOTIC, NEW DRUG, AND NEW ANIMAL

DRUG PETITIONS, APPLICATIONS, AND FORMS

225. The proposed regulations published in May 1972 contained specific amendments to existing regulations dealing with color additives, food additives, new animal drugs, new human drugs, and antibiotic drugs. Many of the provisions present issues that are common to some or all of these regulations, as well as to the provisions in § 4.111 *Data and information submitted voluntarily to the Food and Drug Administration.* For example, the handling of requests for disclosure of test protocols, assay methods, adverse reaction reports, and manufacturing methods must be the same for all of these various types of documents.

Accordingly, the Commissioner has grouped together all of the comments relating to common issues for purposes of analysis and discussion in this preamble.

226. Questions have been raised with respect to the status of data and information submitted to the Food and Drug Administration in "master files" which are subsequently used to support individual petitions or applications. It was suggested in comments that all master file material should remain confidential.

The Commissioner advises that data and information contained in a master file have the same status that they would have in a petition or application. The fact that they are included in a master file rather than directly in a petition or application is of no relevance.

227. Several comments questioned the source of the "public policy," referred to in paragraph 5 of the preamble to the proposal, which favors an expanded public disclosure of research data on safety, functionality, and effectiveness in contrast to the position the Food and Drug Administration has taken since 1938 that all such data and information ordinarily represent valuable commercial property and trade secrets that must be retained as confidential. It was suggested that the relevant "public policy" to be considered was that set forth in the House and Senate reports and in the Attorney General's Memorandum. The point made in the House report that "a citizen must be able to confide in his Government" was stressed as was the statement in the Attorney General's Memorandum that "[w]here similar property in private hands would be held in confidence, such property in the hands of the United States should be covered under exemption (b)(4)."

The Commissioner advises that the "public policy" referred to in paragraph 5 of the preamble to the proposal is that expressed in the Freedom of Information Act. It is the responsibility of the Food and Drug Administration to conform with this mandate of Congress regardless of what its own past policies may have been.

The Commissioner concludes that the final regulations manifest a proper balance between the general statutory objective of releasing all records unless they are exempt and the specific statutory exemptions for trade secrets. Those records that do represent valuable commercial information in that they provide a competitive advantage, will not be disclosed to the public.

228. A number of comments requested clarification of the intended scope of "safety,

effectiveness, and functionality data" under the regulations.

The Commissioner advises that this phrase encompasses all data from animal and human tests designed to show safety and effectiveness, and all studies and tests conducted to establish the basic identity, stability, purity, potency, bioavailability, performance, and usefulness of the product. It does not include quality control tests continuously conducted on a manufacturing process and a product to establish its adherence to process and product specifications or adverse reaction reports obtained upon marketing of a drug or similar information. All of the regulations involved have been revised to reflect this policy.

229. Requests have been made for safety, effectiveness, and functionality data and information contained in letters requesting opinions on the food or feed additive or new drug or new animal drug status of products or ingredients.

The Commissioner advises that matters will be handled as follows:

a. If the request relates to the status of a food or feed ingredient, the safety and functionality information will be made available to the public immediately.

b. If the request relates to the status of a drug or animal drug under the act, a decision as to what information is disclosable must await the response of the Food and Drug Administration to the request. If it is decided that the drug does not require a new drug application or new animal drug application, the safety and effectiveness data will be made available for public disclosure. If the decision is that a new drug application or new animal drug application is required, such data and information will remain exempt from disclosure as trade secrets except to the extent that any of it has been previously been made public. This is the procedure presently being followed under the OTC drug review pursuant to § 330.10(a)(2) of the regulations (21 CFR 330.10(a)(2)).

SAFETY, EFFECTIVENESS, AND FUNCTIONALITY DATA AND INFORMATION CONTAINED IN COLOR ADDITIVE, FOOD ADDITIVE, AND ANTIBIOTIC DRUG PETITIONS AND FORMS

230. The proposed regulations published in May 1972 established the same rules for release of safety, functionality and effectiveness data contained in color additive, food additive, and antibiotic petitions and forms. Under the Federal Food, Drug, and Cosmetic Act, these three types of petitions and forms result in public regulations rather than private license, although antibiotic drugs are subject to the IND provisions of the law prior to approval for marketing. Accordingly, it was concluded that the safety, functionality, and effectiveness data do not fall within the trade secrets and confidential commercial information exemption and thus are properly made available for public disclosure regardless of whether the petitioner has previously made this information public.

All of the comments received with respect to the handling of these matters have been grouped together for purposes of analysis and discussion in this preamble.

231. It was pointed out in some comments that this was a direct about-face from the previous

position of the Food and Drug Administration. It was urged that data contained in food and color additive petitions and antibiotic drug forms be disclosed only to Food and Drug Administration consultants, advisory committees, and special government employees, and not to the public.

The Commissioner notes that there was no clear policy on this matter in the past, and that in any event the policy of the Food and Drug Administration prior to enactment of the Freedom of Information Act is not determinative with respect to proper implementation of the Freedom of Information Act at the present time. The Commissioner concludes that the safety, functionality, and effectiveness data contained in food and color additive petitions and antibiotic drug forms have no trade secret value and, since they are often published in scientific journals or given to customers or scientists or disclosed to the public in other ways, are not customarily regarded as privileged. Accordingly, this type of material does not qualify as confidential either under the trade secret portion of the exemption or under the confidential commercial and financial data portion of the exemption. This is in contrast to other information, such as manufacturing procedures, which are not customarily so disclosed or made public.

232. Several comments objected to the statement in paragraph 5 of the preamble to the proposed regulations published in May 1972, to the effect that research data for food additives and color additives are "not the type of commercial information customarily regarded as privileged."

The Commissioner disagrees with this comment and affirms the statement made in the preamble to the proposed regulations. A number of comments filed by food ingredient manufacturers did not object to the release of safety and functionality data for food additives and color additives. In the intervening 2 years, all such data have been made available to the public. Although affected manufacturers were permitted an opportunity to contest such disclosure in the courts, no such lawsuits were filed. Some manufacturers have, indeed, affirmatively agreed to the disclosure of such information. Information of this type is routinely published in the scientific literature or otherwise distributed to interested scientists, potential customers, and others. Accordingly, the Commissioner concludes that it is not customarily regarded as confidential commercial information.

233. A comment suggested that safety, effectiveness, and functionality data for food additives, color additives, and antibiotic drugs do provide an advantage over competitors because they can be referred to in promotional and selling activities.

The Commissioner rejects this comment. Once such ingredients or products are approved by the Food and Drug Administration for distribution generally, the use of such data by a particular manufacturer for promotional activities cannot reasonably be regarded as providing a competitive advantage.

234. One comment contended that, even if food additive and color additive safety and functionality data provide no competitive advantage in the United States, they do provide a substantial competitive advantage in obtaining governmental approvals in foreign countries. The Commissioner concludes that the possibility that such data and information may at some

future time permit competitive advantage in some foreign country is too conjectural and remote to permit the conclusion that all such data and information fall within the trade secrets exemption. In the event that specific facts are available to show such a competitive advantage with respect to a particular matter in a specific foreign country, the Commissioner will evaluate the situation to determine whether it presents the "extraordinary circumstances" under which the material will not be disclosed pursuant to the final regulations.

235. With regard to the safety , effectiveness, and functionality data for food and color additive petitions and antibiotic drugs, comments stated that there was no justification for withholding information until the regulations are issued. It was argued that, if this information does not provide a competitive advantage when such approval is granted, since all manufacturers are then free to make the product, it is questionable whether the information provides any competitive advantage prior to approval, since no manufacturer may market or use the product until then. It was urged that, when the approval is granted for minor variations in formulations of such ingredients or products, any competitive advantage is insignificant, considering the little time it would take a competitor to start production by using the information published in the regulation. As a positive benefit, it was argued that release before the regulation was issued might trigger research which might contribute to the making of a more reasoned decision on the petition or antibiotic drug form.

The Commissioner agrees with the substance of this comment. Accordingly, the final regulations provide that the safety and functionality data contained in color additive and food additive petitions will be made available for public disclosure when the notice of filing of the petition is published in the FEDERAL REGISTER. Where such notice of filing is substantially delayed, because the petition does not contain sufficient information and further testing is required, the safety and functionality data submitted will be available for public disclosure after the review of the submission by the Food and Drug Administration is complete and the petitioner has been informed of the deficiencies. Similarly, the safety and effectiveness data contained in an antibiotic drug form will be available for public disclosure when the Food and Drug Administration issues an approval letter to the manufacturer. This usually occurs a substantial time before an antibiotic drug monograph is published in the FEDERAL REGISTER.

The Commissioner believes that this approach adequately accommodates any legitimate desire of industry to maintain the confidentiality of its data until a reasonable time before approval, the need for the Food and Drug Administration for review and evaluation of the submission before it is released to the public, and the right of the public for access to the data and information submitted in order to make meaningful comments on it within the time permitted.

236. Comments suggested that if food and color additive petitions and antibiotic drug forms are not customarily privileged, manufacturers should not be permitted to show "extraordinary circumstances" to justify nondisclosure. It was emphasized that no "extraordinary circumstances" may be created by a manufacturer's plea where the Freedom of Information Act exemptions do not apply.

The Commissioner advises that the provision permitting a manufacturer to show "extraordinary

circumstances" to justify nondisclosure was included in the event that, on rare occasions, circumstances may arise that cannot be foreseen at this time which would require, in fairness, that material not be disclosed. The Commissioner anticipates that this will happen on very few occasions, and that in almost all instances this type of information will promptly be released to the public. In order to show "extraordinary circumstances," the manufacturer must demonstrate that release of the information will destroy a competitive advantage that he would otherwise enjoy, that he will be hurt financially as a result, and thus that it would be unlawful or unfair to release the information involved. The mere fact that the information may be embarrassing, or may require removal of a product from the market, or may disclose adverse reactions, or may be of interest to others, or that there is some remote future possibility of competitive advantage, or that others might conduct duplicative research which would be obviated by release of the information, or similar arguments, will be insufficient to justify nondisclosure.

237. Following publication of the proposed regulations in May 1972, some food additive petitions were submitted to the agency marked "confidential" or accompanied by letters stating the opinion that the information contained therein was confidential.

In each of these instances, the Food and Drug Administration responded stating that the petition was being filed without any pledge of confidentiality. In order to clarify this matter, the Commissioner is including in new § 4.27 of the final regulations a statement that any such gratuitous designation by a person submitting a petition or application is of no legal effect, and that the only pledges of confidentiality that will be made by the Food and Drug Administration are contained in this final regulations themselves and through the procedure established in new § 4.44 of the regulations.

SAFETY AND EFFECTIVENESS DATA FOR NEW DRUGS AND NEW ANIMAL DRUGS

238. The proposed regulations published in May 1972 established the same rules for release of safety and effectiveness data contained in new drug and new animal drug applications. Under the Federal Food, Drug, and Cosmetic Act, these applications, and the notices relating to investigational use of new drugs, result in private licenses rather than in public regulations. Accordingly, it was concluded that the safety and effectiveness data for new drugs and new animal drugs, including antibiotic drugs for veterinary use, fall within the trade secrets exemption and thus are not available for public disclosure unless the applicant has previously made the information public or the drug has been disapproved or withdrawn from the market or the drug has reached the stage where it may be marketed without submission of such data to the agency for approval.

All of the comments received with respect to the handling of these matters have been grouped together for purposes of analysis and discussion in this preamble.

239. Comments suggested that the provision in the proposed regulations, that the existence of an IND will not be disclosed unless it has previously been "acknowledged" by the sponsor, is too vague; and that the term "publicly disclosed" should be substituted for "acknowledged."

The Commissioner concurs in part with this comment, and uses the phrase "publicly disclosed or acknowledged" in the final regulations. Private acknowledgment of the existence of an IND to a consultant is insufficient to constitute public disclosure. Discussion with other scientists who are not paid consultants, however, or with securities analysts, or acknowledging the existence of an IND to any such person, is sufficient to break the confidentiality of the existence of an IND. The Commissioner notes that the existence of an IND is often common knowledge within the industry and the scientific world, and that confidentiality of such information is becoming more and more unusual.

240. Questions have arisen as to whether the existence of an IND notice can be regarded as confidential commercial information if the drug is marketed abroad or if published literature exists on the drug.

The Commissioner concludes that the existence of an IND notice under these circumstances will not be regarded as confidential. The marketing of a drug abroad or the publication of information about the drug constitutes public notice of the existence of the drug entity and the probability that the company will be considering marketing it. In particular, scientific discussion of the drug in the United States, in the literature or in meetings, clearly discloses the existence of an IND.

241. Requests have been received for the names and addresses of all investigators with respect to an investigational new drug where the existence of the IND notice has been publicly disclosed or acknowledged.

The Commissioner concludes that a list of all such investigators is confidential commercial information. If such a list were disclosed, there would be a good possibility that competitors could determine the progress of the investigation, or that patients would seek out the investigators to determine whether they might also receive the investigational drug, or that the value of the study could be destroyed by outside interference.

242. A request was received for the curriculum vitae of a specific person who is publicly known to be an investigator for a particular new drug.

The Commissioner concludes that a curriculum vitae is properly available for public disclosure under these circumstances. Information contained in a curriculum vitae is customarily distributed in a public fashion, and accordingly such release does not constitute an unwarranted invasion of privacy.

243. A comment contended that all IND information should be available, whether or not the IND has been terminated, for the protection of the human subjects involved in the drug experiments. The comment stated that there is increased danger in testing subjects because of the Food and Drug Administration policy of allowing drug companies to experiment on human beings before animal tests are completed. Without disclosure, it was stated, there is also no incentive for following up on patients who have taken experimental drugs.

The Commissioner concludes that the present law precludes such release of the safety and effectiveness data in an active IND file unless it has previously been publicly disclosed. The remedy for the individual who has participated in the testing of a new drug is to obtain information about the drug from the drug company involved. Current Food and Drug Administration regulations require such disclosure, and the individual to be tested also has the option of not participating in the test unless there is full disclosure of all information, including, in particular, the adverse effects of other test subjects, and a petition relating to requirements for animal tests before human tests, are presently under active consideration.

244. Comments contended that, once an IND is terminated, there is no public benefit to be obtained from the disclosure of information in it.

The Commissioner concludes that "public benefit" is not a criterion for determining whether information shall be disclosed to the public under the Freedom of Information Act. Moreover, in many instances there will be a definite public benefit from such disclosure.

245. Comments stated that even the irrevocable and final termination of an IND in this country should not result in disclosure of the safety and effectiveness information contained in it if the same drug is being marketed elsewhere in the world.

The Commissioner does not agree with this comment. Even the pharmaceutical industry's comments generally agreed that a summary of safety and effectiveness information can properly be disclosed to the public without violating the trade secrets and confidential commercial information provisions of the law. It is only the full reports that may not properly be disclosed, because the Federal Food, Drug, and Cosmetic Act requires that such full reports are necessary in order to obtain an approved NDA. If the terminated IND contains adverse information with respect to safety and effectiveness, therefore, a summary of that information could properly be released, and would be as damaging to foreign marketing as would the full reports of such information.

Moreover, none of the comments submitted demonstrated any likelihood that the full reports of such information, as contrasted with summaries, are required under foreign law in order to justify marketing abroad. The Commissioner therefore concludes that any such possibility of competitive advantage is too conjectural and remote to justify invoking the trade secrets exemption of the Freedom of Information Act. Should a specific instance arise in which a competitive advantage can be demonstrated in concrete terms, a manufacturer is permitted to support nondisclosure of such information under the "extraordinary circumstances" exemption provided in the final regulations.

246. In at least two instances, manufacturers have requested that an IND not be terminated for fear that such termination, in and of itself, would result in the information in the IND becoming available for public disclosure.

The Commissioner advises that the termination of an IND is not dispositive with respect to the

availability of information contained therein. If the company can demonstrate that the matter is still under active development, such information will retain its trade secret status.

RULES AND REGULATIONS

247. In one instance, a request was made for information contained in an IND file for which human clinical studies had been discontinued as a result of adverse animal findings. The company requested continued confidentiality of the information in the file on the ground that it was pursuing additional animal studies in order to reactivate the IND file and intended eventually to pursue an NDA.

The Commissioner concludes that, under these circumstances, safety and effectiveness information contained in an IND file that is otherwise confidential will remain confidential. An IND is terminated or abandoned only after all human and animal work with respect to the drug has been discontinued, and the data and information contained in an IND which are otherwise confidential will not be disclosed to the public as long as the matter remains open and active. Where the issue is in doubt, the Food and Drug Administration will require submission of further information from the person who submitted the IND. Any statement relating to the future intentions of that person with respect to the IND would be subject to the False Reports to the Government Act, 18 U.S.C. 1001.

248. One comment suggested that the IND provision be clarified to state that approval of an NDA, which technically results in termination or discontinuance of an IND, does not require release of all of the confidential information contained in the IND.

The Commissioner advises that the IND and NDA are regarded as one continuous process. Indeed, the NDA incorporates the IND the material in the IND has the same status as the material in the NDA. Accordingly, upon the filing or approval of an NDA. The final regulations make this clear.

249. The proposed regulations published in May 1972 provided that a list of pending new drug applications would be available for public inspection.

On reconsideration, the Commissioner has concluded that such a list should be made available only for new drug applications for which the applicant has been advised that NDA is "approvable," and not for all pending new drug applications. The existence of pending NDA constitutes confidential commercial information where the existence of clinical testing has not previously been publicly disclosed or acknowledged. Accordingly, the final regulations have been revised to state that the list will include only
those new drug applications where the company has been advised by the Food and Drug Administration that the NDA is approvable.

250. Comments stated that the fact that a company has filed an IND or is even interested in a

particular pharmaceutical area may will be a trade secret.

The Commissioner concludes that such information, although not a trade secret, is properly regarded as confidential commercial information that will not be disclosed to the public by the Food and Drug Administration unless it has previously been disclosed or acknowledged to any member of the public.

251. Comments asserted that knowledge of a pending NDA or NADA will almost always afford a competitor an advantage because he will then be in a position to adjust his marketing strategy in anticipation of a competing product. Hence the very fact that an NDA is pending will frequently be a trade secret.

The Commissioner agrees that the fact that an NDA or NADA is pending is confidential commercial information that will not be disclosed if it has not previously been publicly acknowledged or disclosed. The trade press often reports that an NDA has been submitted or is pending before the agency and frequently a company will make such information public in its reports to stockholders.

252. Undoubtedly the most persistent issue raised in the comments relates to the disclosure of safety and effectiveness data in IND and NDA files. Comments requesting disclosure of all such information quite properly pointed out that it is important to scientists and physicians. Comments opposing disclosure of this information quite properly pointed out that it is of enormous economic value.

The Commissioner concludes that there can be no question, under present law, about the tremendous economic value of the full reports of the safety and effectiveness data contained in an IND, NDA, INAD, or NADA. Such information costs hundreds of thousands, and is some instances millions of dollars to obtain. Release of such information would allow a competitor to obtain approval from the Food and Drug Administration for marketing the identical product. Present law contains no provision that would permit the Food and Drug Administration to refuse to approve a "me-too" product on the basis of information obtained from the first manufacturer, once that information from the first manufacturer is disclose.

The Commissioner recognizes the important public policy issues that would be raised by disclosure of such trade secret data. The public is dependent upon private pharmaceutical manufacturers for development of drugs. In some instances those drugs may be patented, but in other instances they may not be patented. If a manufacturer's safety and effectiveness data are to be released upon request, thus permitting "me-too" drugs to be marketed immediately, it is entirely possible that the incentive for private pharmaceutical research will be adversely affected.

The Commissioner does not believe that this issue can or should be addressed by the Food and Drug Administration alone. Rather, it is an important public policy issue that can and should be addressed primarily by Congress. Accordingly, the Commissioner concludes that, if any change is to be made in the handling of the full reports of the safety and effectiveness data submitted to the agency as part of an IND, NDA, INAD or NADA, it should properly be made by Congress through new legislation, and not by the Food and Drug Administration through these regulations.

253. Comments argued that the treatment of trade secrets in the proposed regulations is circular since the "competitive advantage" acquired is one that is based on the Food and Drug Administration's own regulatory scheme.

The Commissioner concludes that there does not appear to be any legal or policy reason why a "competitive advantage" for purposes of determining whether information is a trade secret may not be one obtained from a statutory scheme. The existing regulatory scheme is one created by the Congress and not by the Food and Drug Administration. Data that no longer provide a competitive advantage - because any competitor may lawfully market the product involved, or because the information has otherwise been made public, or for other reasons - no longer qualify as a trade secret under 18 U.S.C. 1905, 21 U.S.C. 331(j), or the Freedom of Information Act.

254. A comment objected to the withholding of NDA information on the ground that it grants a monopoly that continues forever, since in order to market an approved drug a company must do all the testing required to show safety and effectiveness. It was pointed out that this may cost millions of dollars and has the effect of limiting the market to the company that did the original testing and to those other companies which are permitted by a first company to incorporate by reference its safety and effectiveness data into their applications. This system, referred to as a "domestic cartel," bars production of a drug because of the expense of reproducing the test data, irrespective of whether the patent has expired or is declared invalid or whether the product is unpatentable because it is a "product of nature" or lacks novelty. Further, it was asserted that, once a drug was tested, there was no social gain in requiring duplication of the testing by other companies.

The Commissioner advises that the Federal Food, Drug, and Cosmetic Act require full reports of safety and effectiveness from each company submitting an NDA. The Food and Drug Administration has, on a number of occasions, pointed out to Congress the effect of this requirement, and has suggested that Congress consider whether this policy should be retained or changed. Congress has, to date, not taken action on this matter.

255. Comments questioned whether animal and human data on safety and effectiveness can be considered a "method or process which as a trade secret is entitled to protection", within the meaning of section 301(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 331(j)).

The Commissioner advises that, since 1938, it has been the consistent administrative interpretation that this statutory provision can encompass animal and human data, although the agency did not previously have a clear policy as to when such data did or did not represent trade secrets. This longstanding interpretation has been set out in Food and Drug Administration manuals, in advisory opinions, and in testimony to Congress. Accordingly, the Commissioner concludes that it would be improper for the Food and Drug Administration to make an administrative determination reversing that position at this time. Moreover, regardless of the scope of section 301(j), the Commissioner concludes that the provisions of 18 U.S.C. 1905 and the trade secrets exemption to the Freedom of Information Act are clearly applicable to such data.

This issue was recently considered in the case of "Morgan v. FDA," 495 F.2d 1075 (D.C. Cir. 1974). The District Court ruled that the data on safety and effectiveness contained in a new drug application are exempt from disclosure under all three statutes. The Court of Appeals rule that such data can properly be encompassed within the trade secrets exemption to the Freedom of Information Act.

256. Comments contended that the new drug license system results in "superpatents," and that by using drug licensing to create a second patent system the Food and Drug Administration permits companies to settle private patent disputes by cross-licensing.

The Commissioner advises that it is Congress, not the Food and Drug Administration, that has created the new drug licensing system. The Commissioner believes that the Department of Justice and the Federal Trade Commission have full legal authority to prevent any collusive cross-licensing agreements within the pharmaceutical industry. In any event, it is well recognized that a person who owns a property right of any type may contract with others for its use. Thus, a company may sell its rights in an NDA or may license others to refer to it.

257. Comments suggested that public policy supports the release of all safety and effectiveness data for new drugs, and contended that summaries of such data are insufficient to afford adequate scientific review. It was pointed out that the President's Commission on Federal Statistics recommended in 1971 that all such information should be released. Comments suggested that the procedure for release of this type of information contained in the Federal Environmental Pesticide Control Act of 1972 (Pub. L. 92-516, 86 Stat. 973) should be used.

The Commissioner agrees that public policy supports release of all safety and effectiveness data, but points out that present statutory law, 18 U.S.C. 1905 and 21 U.S.C. 331(j), prohibits such release. The Federal Environmental Pesticide Control Act of 1972 contains a statutory mechanism for protecting a manufacturer's property right in trade secret data. The Commissioner has no authority to institute such a system without statutory authorization from Congress.

258. The proposed regulations published in May 1972 would have required every holder of a previously approved NDA or NADA to summit a summary of confidential safety and effectiveness data, and every person submitting such an application in the future to include such a summary, which would then be revised by the Food and Drug Administration and publicly disclosed. Present Food and Drug Administration regulations require that an NDA or NADA contain a short or expanded summary of all of the information contained in the application. In addition, these applications are review thoroughly by Food and Drug Administration personnel who prepare internal memoranda summarizing the information they contain, evaluating it, and setting out their conclusions and recommendations on it. During the past 2 years, requests have been made for the various summaries in NDA files prepared by the medical officer, the pharmacologist, the chemist, and in some instances, the biostatistician.

The Commissioner concludes that, in view of the fact that the full reports of the safety and effectiveness data contained in an approved NADA or NDA that have not previously been disclosed to the public constitute trade secret information that is prohibited from public

dissemination pursuant to 21 U.S.C. 331(j) and 18 U.S.C. 1905, if is important that summaries of all such data and information be made available so that scientists and members of the public who are interested will have an opportunity to determine the basis on which Food and Drug Administration decisions are made. Accordingly, the Commissioner has concluded that summaries of the safety and effectiveness data and information on the basis of which an NDA or NADA has been approved should be made publicly available.

a. The Commissioner recognizes the difficulty involved in implementing this decision for previously approved NDA's and NADA's. It is not administratively feasible to prepare new summaries at this time for all such prior approvals. Accordingly, for such prior approvals the Commissioner has concluded that internal agency records that describe such information will be made available for public disclosure upon request. It is not possible to state exactly which internal records will be adequate to convey this information, because this may vary depending upon the bureau involved, the administrative procedures being followed at the time the approval was granted, and various other factors. Such records will include internal reviews of the data and information, action memoranda, a summary of the basis for approval, or other internal memoranda sufficient to describe the safety and effectiveness data and information for the drug involved.

The Commissioner also recognizes that many of these old memoranda were prepared solely for internal consideration, and may contain information that is not proper for public disclosure. For example some memoranda may mention the names of patients in an IND study. Some of these memoranda also contain criticism of investigations to which the investigators have never had an opportunity to respond and other inappropriate gratuitous comments unnecessary to an objective presentation of the data and information. If these memoranda had been prepared for public dissemination, such information and comments would not have been included. Accordingly, the Commissioner concludes that the names of patients and investigators and inappropriate comments will be deleted prior to public disclosure.

On the other hand, the Commissioner concludes that the analysis, discussion, conclusions, and recommendations contained in such memoranda should not be deleted. Such material could properly be withheld from public disclosure in accordance with the exemption for intra-agency memoranda, but the Commissioner believes that public discussion of these matters is better served by disclosure of all of the conclusions and recommendations set out in the memoranda, with only the minimal deletions mentioned above. In some instances, this will disclose recommendations which the Food and Drug Administration concluded not to follow at the time, or decisions which have subsequently been reversed. The Commissioner believes that such disclosure will not harm the regulatory efforts of the agency, but indeed will serve to foster better public understanding of the internal discussion about scientific and medical issues that must always characterize an open and responsive regulatory agency.

b. For NDA's and NADA's approved in the future, the Commissioner concludes that somewhat different rules should apply. Rather than disclosing internal discussion memoranda, it is more appropriate to provide for preparation of a single institutional summary stating all of the data and information relating to the safety and effectiveness of the product on the basis of which the agency

action was taken. Moreover, rather than wait until a request is made for such a summary, it will be publicly released when the approval is made.

It is not administratively feasible immediately to implement this new requirement. Accordingly, the Commissioner concludes that NDA's and NADA's approved on or after July 1, 1975, will be the subject of such an institutional summary of the safety and effectiveness data and information. This will provide sufficient time for the Bureau of Drugs and the Bureau of Veterinary Medicine to prepare guidelines for such summaries and to implement this new policy for those applications now undergoing review within the agency.

The Commissioner concludes that, for these future approvals, the summary may be prepared in one of two alternative ways. First, the relevant bureau may request the applicant to prepare a summary of all of the data and information for this purpose, which the bureau will then review, revise, and release at the time that the drug is approved. It would obviously be premature to require that this summary be submitted with the NDA or NADA. Rather, where this alternative is utilized, the bureau will request submission of such a summary at an appropriate time near approval of the application, when it is likely that all of the data and information will have been submitted and fully considered.

The second alternative way for preparing such a summary will be for the bureau to prepare its own summary, without requesting the applicant to submit a summary for this purpose. The Commissioner concludes that this approach may well be appropriate where the application and internal memoranda already contain various summaries and the bureau decides that submission of another unnecessary.

Once the requirement for an institutional summary goes into effect on July 1, 1975, it will no longer be necessary or appropriate for the Food and Drug Administration to release other internal discussion memoranda relating to approval of NDA's and NADA's. This institutional summary will collate and distill all of the numerous internal memoranda relating to these matters, and thus will set forth in a comprehensive way the basis for the approval. Since it will purposely be prepared for public dissemination, it is unnecessary for the final regulations to state that these new summaries will not violate personal privacy or otherwise contain inappropriate material.

c. Finally, the Commissioner, notes that the rules pertaining to summaries set out in the final regulations apply to supplemental and abbreviated NDA's and NADA's as well as to original NDA's and NADA's. On the other hand, not every supplemental or abbreviated NDA or NADA is sufficiently different to justify a new summary. Accordingly, it will be left to the judgment of the bureau to determine whether the original summary for an NDA or NADA will require revision or supplementation to reflect changes made by approval of a supplemental NDA or NADA. Where a new use or substantially different dosage is approved such revision would undoubtedly he required, but where only such matters as manufacturing controls or ingredient sources are involved no change would be warranted.

259. A number of comments from the pharmaceutical industry agreed with the concept of making public a summary of the information on safety and effectiveness in approved new drug

applications. Some comments agreed with the proposal that this should be a specially prepared summary, and some suggested that it should be the summary already provided in the NDA.

The Commissioner concludes that the rules for preparation and disclosure of summaries set out in the final regulations are adequate to provide for information to the public on the safety and effectiveness data on the basis of which an NDA or NADA is approved, with minimum disruption to the applicant and the Food and Drug Administration. The Commissioner concludes that it would be unduly burdensome to require preparation of new summaries for previously approved drugs, and that internal memoranda should be sufficient to describe the basis for these past decisions. The Commissioner also concludes that the institutional summary to be prepared and released to the public for all approvals after July 1, 1975, may properly be prepared solely by the bureau involved, or may be based upon a summary specially submitted by the applicant for that purpose. None of these summaries will be sufficient for a competitor to satisfy the statutory requirement for "full reports" of safety and effectiveness in order to obtain his own approved application, and thus the trade secret status of the underlying data and information will be preserved. If the Commissioner determines that this is not successful in providing adequate summaries of the safety and effectiveness data to the public, the matter will be reopened for consideration of alternative methods of achieving this purpose.

260. The question was raised in comments as to what was meant by "a summary of the safety and effectiveness data and information submitted" which was proposed to be submitted with each NDA for release to the public. It was suggested that a "general" summary should suffice for the needs of the practicing physician, the consumer, and the scientific community. A "detailed" summary, it was believed, would ease the burden of a subsequent new drug applicant in this country and might also enable such a manufacturer to market in other countries with little or no testing. It was also indicated that a detailed summary might well constitute prior disclosure under the patent laws of one or more foreign countries and therefore prevent the original NDA holder from obtaining patient protection in those countries. It was also suggested, because of the trade secret and otherwise confidential nature of the underlying data involved, that the manufacturer should have the final say on the content of any such summary, and that no summary change be made without the consent of the manufacturer.

The Commissioner concludes that the summaries to be released pursuant to the final regulations will not ease the burden on a subsequent new drug applicant in this country since such an applicant would nonetheless be responsible for running the required tests. The Commissioner concludes that the possibility of competitive advantage abroad is speculative and remote. Although in some instances the bureau may wish to confer with others, including the applicant, in preparing the institutional summary, this is not required and under no circumstances will the applicant have the final say on its contents.

261. Comments asked whether submission of a summary is required each time a supplemental NDA is filed. This, it was indicated, would be an unnecessary duplication since the supplement is often directed to some rather minor change in the labeling of the product with no relevance to the previously submitted safety and effectiveness data.

The Commissioner advises that, under the final regulations, a summary will be released for a supplemental NDA or NADA where the supplemental application has a significant impact on safety or effectiveness. It is unnecessary specifically to mention supplemental applications in the regulations because a supplemental application becomes part of the original application. Thus, consideration of revision or supplementation of a summary is required whenever a supplemental application is approved.

262. Comments complained that disclosure of summaries of safety and effectiveness data does not serve the purpose of the Freedom of Information Act since outside scientists need the raw data in order to determine whether the agency has acted wisely in a given instance. It was contended that release of a summary would serve only as a "public relations stunt" for the industry.

The Commissioner concludes that the present law provides the Food and Drug Administration a choice between release of a summary or release of no safety and effectiveness information, since release of the complete data would constitute disclosure of a trade secret prohibited by 21 U.S.C. 331(j) and 18 U.S.C. 1905. The release of a summary is preferable to no release of information. The summary will be complete enough to convey both the nature of the experiment and the scientific data generated.

263. Questions have arisen as to whether the Food and Drug Administration may release adverse safety data submitted by a manufacturer as part of an IND file or a pending NDA.

The Commissioner concludes that the full report and data may not properly be released, but that a summary of such data may be released, if the existence of the IND or pending NDA is itself not confidential. If the existence of the IND or pending NDA is itself confidential, release of a summary of adverse safety data would not be permitted.

Because the Commissioner concludes that the full administrative record of an IND or pending NDA represents confidential commercial information prior to approval of an NDA, a summary of safety or effectiveness data in an IND or pending NDA shall be made public only on a selective basis, in a way that will not reveal the full administrative record. Such a situation usually occurs when the matter is under consideration by a Food and Drug Administration advisory committee. This policy is reflected in § 314.14(d) of the final regulations.

264. Foreign governments have discussed with the Food and Drug Administration the possibility of exchanging data and information on the safety and effectiveness of investigational and marketed drugs.

The Commissioner concludes that the same rules will apply with respect to disclosure of such information to foreign governments as apply to disclosure to the public. This will permit the Food and Drug Administration to provide full summaries of all safety and effectiveness data for all approved NDA's and selected summaries for IND's and pending NDA's for which the existence of an IND has been publicly disclosed or acknowledged. The Commissioner concludes that this will adequately satisfy the need for international exchange of important regulatory

information of this type.

265. Comments were received that adverse safety and effectiveness information, which might lead to a reduction in use of a drug or to withdrawal of the drug from the market, is properly regarded as confidential commercial information because it can adversely affect the sales of the product. Other comments, however, did not distinguish between adverse and favorable information, and concluded that the Food and Drug Administration could properly release summaries of all material relating to safety and effectiveness.

The Commissioner concludes that a summary of adverse safety and effectiveness information may properly be made available for public disclosure. As already discussed, such information is commonly published in the scientific literature and distributed to the scientific community. Accordingly, it cannot be said to be said to be customarily held in strict confidence.

266. A comment stated that, for an NDA which is not approved, a summary of the basis of the refusal should be released.

The Commissioner advises that the disapproval letter and all data from an NDA which has received final agency disapproval will be available for disclosure after all administrative and judicial appeals are exhausted. However, such records will be released only where the agency disapproval is final, and not where there is merely an intermediate determination of insufficient data for approval and the applicant continues the work needed to obtain approval.

267. Comments contended that all data and information contained in an NDA are properly held in confidence forever by the Food and Drug Administration, and thus cannot be disclosed when the drug is withdrawn or becomes an old drug or for any other reason, because (1) the legislative history of 21 U.S.C. 331(j) indicates that all such information was to be regarded as trade secrets, (2) the Food and Drug Administration has in any event obligated itself to maintain the confidence of this information by promises made to industry since 1938, and (3) the agency is precluded from changing its consistent administrative interpretation of the law under the doctrine of "Udall v. Tallman," 380 U.S. 1 (1965).

The Commissioner concludes that the legislative history of 21 U.S.C. 331(j) shows that Congress simply did not decide the issue raised in these regulations. Although Congress stated that all trade secrets in new drug applications were to remain confidential, it did not, in the reports or legislative debate, consider or define the intended scope of the term "trade secret."

The Food and Drug Administration has since 1938 pledged that all trade secret information contained in a new drug application will be held in confidence, and has stated that animal and human tests can fall within that section. The Food and Drug Administration has not previously adopted a specific definition of "trade secret", however, or delineated the precise circumstances under which animal and human data do or do not constitute trade secrets, or otherwise attempted to set out the scope of that provision of the law in the detail that is done in these regulations and this preamble. Moreover, Congress has now enacted the Freedom of Information Act, establishing new public policy, which requires reevaluation and clarification of the agency's prior

policy.

The Freedom of Information Act contains a congressional mandate to release all information not explicitly prohibited or exempt from public disclosure. The proposed regulations published in May 1972 represent the Food and Drug Administration's first attempt to interpret and apply that directive. The Commissioner believes that the policy proposed there, and adopted in these final regulations, represents a reasonable accommodation or both the disclosure provisions of the Freedom of Information Act and the nondisclosure provisions contained in 21 U.S.C. 331(j), 18 U.S.C. 1905, and the trade secrets exemption from the Freedom of Information Act, insofar as they apply to trade secrets and other confidential commercial information.

268. Comments contended that the fact that a product is not currently being marketed or has been withdrawn from the market does not prevent that product from being entitled to trade secret protection, citing "Harris Manufacturing Co. v. Williams," 157 F Supp. 779 (W.D. Ark. 1957); and "Ferroline Corp. v. General Aniline Corp.," 207 F.2d 912 (7th Cir. 1953).

The Commissioner does not concur with this comment, and believes that the cases do not support the proposition for which they are cited. In the "Harris" case, the court noted that the plaintiff had not abandoned use of the product in question, and stated that the mere fact that a company is not using a particular product at a particular time does not prevent it from being a trade secret. The final regulations make it clear that termination or disapproval of an IND or NDA refer to final termination or disapproval, not to some intermediate step. As is discussed elsewhere in the preamble, continued pursuit of the IND or NDA will be sufficient to justify the continued confidentiality of the safety and effectiveness data involved.

In the "Ferroline" case, the company had conveyed by contract its rights to the trade secret to another party, and then later regained the rights to that trade secret and attempted unsuccessfully to re-enter the field. The gravamen of its complaint was that the misappropriation of the trade secret by the defendants precluded successful reentry. The court held that the plantiff was entitled to bring the suit notwithstanding the fact that it currently was not utilizing the trade secret in question. The Commissioner concludes that the circumstances of this case are totally different from any of those involved in the final regulations, and thus that this case is of little, if any, relevance. The final regulations do recognize that a property right in a trade secret may be conveyed by contract. In the "Ferroline" case, however, the non-use of the trade secret was caused by the alleged breach of confidentiality, whereas in the final regulations promulgated by the Commissioner there can be no authorized released until the product is not currently being marketed or has been withdrawn from the market.

269. The major argument advanced in comments objecting to the disclosure of IND and NDA safety and effectiveness data after disapproval of the product is that the events upon which disclosure hinges, e.g., termination, discontinuance, approval, etc., are actually irrelevant to the issue of whether or not the information is a trade secret. It was contended that a number of competitive advantages continue to exist or later accrue after such an event occurs. It was asserted that simply knowing a process does or does not work is worth hundreds of thousands of dollars and years of research to a competitor. Further, such information could be used to develop

marketing and sales literature and provides a definite advantage to its owner in obtaining foreign product registrations. The
advantage was thought to be especially strong with respect to marketing in countries where there is little or no patent protection. The advantage in the foreign market situation could, it was suggested, be so great as to create a further imbalance against the United States in foreign trade. It was indicated that a discontinued or terminated IND or NDA may be reviewed and reactivated if there is a change in scientific knowledge. It was argued that drugs subject to termination may be found to have congeners which are safer and more effective, and that initial investigations may indicate a metabolite of the drug under study is the more active form and investigational efforts may be diverted to studies of the metabolite. Comments stated that termination at that point in time to use research money on another drug. The data in an investigational file may later become essential when related drugs are being investigated. Such data can form the basis of cooperative agreements with other drug companies or universities on renewed trials of a drug. Comments contended that the termination of one IND or NDA; and disclosure of trade secrets relating to it may affect another IND or NDA which has not been terminated. It was also pointed out that investigations voluntarily terminated here may be continued abroad.

The Commissioner concludes that termination, in order to trigger disclosure, must be final. If there is some legitimate reason for the termination being only temporary, data and information will not be disclosed. The regulations also permit a showing of "extraordinary circumstances" why data in a terminated file should not be disclosed. A situation in which one IND or NDA directly affects another might be viewed as an extraordinary circumstance. Again, the possibility of foreign competitive advantage is too speculative and remote to justify a broad exemption from disclosure under the Freedom of Information Act.

270. Many comments based objections to the release of any safety and effectiveness data whatever on an affidavit by Henry E. Simmons, M.D., former Director of the Bureau of Drugs, dated April 5, 1971, filed in the United States District Court in the case of "Morgan v. FDA."

The Commissioner advises that the position taken in that affidavit no longer represents the policy of the Food and Drug Administration. Subsequent to the preparation of that affidavit, the Food and Drug Administration made a comprehensive evaluation of the status of safety and effectiveness data for drugs under the Freedom of Information Act for the first time since that law was passed. The results of that evaluation were set out in the proposed regulations published in May 1972 and in the brief subsequently filed by the Food and Drug Administration in the United States Court of Appeals in the "Morgan" case. The recent decision of the United States Court of Appeals in the "Morgan" case explicitly recognizes that, because of the procedural posture of that case, it does not provide precedent for determining the status of all safety and effectiveness data for new drugs. The Commissioner advises that the proper way to decide this issue will be through a declaratory judgment action contesting either the validity of these final regulations or the propriety of proposed disclosure of particular information in a specific instance.

271. Comments argued that, although safety and effectiveness data and information for an old drug may no longer be a "trade secret," they can still be regarded as "confidential commercial

information" because they are not customarily divulged publicly.

The Commissioner rejects this comment. Such data no longer have any commercial value, and indeed no comment suggested any reasonable rationale for such value. Moreover, scientific data are customarily published in the scientific literature or in any event are made available to physicians and scientists for review, and accordingly are not customarily regarded as privileged information.

272. Comments contended that confidentiality of safety and effectiveness data should not cease once a drug becomes an old drug, particularly in light of the fact that, under the decision in "Bentex Pharmaceuticals, Inc. v. Richardson," 463 F.2d 363 (4th Cir. 1972), the Food and Drug Administration has no authority to determine old drug status.

The Commissioner notes that, upon appeal in that case, the Supreme Court held that the Food and Drug Administration has primary jurisdiction to decide the new drug/old drug status of a drug. "Weinberger v. Bentex Pharmaceuticals, Inc.," 412 U.S. 645 (1973). Since the agency will be in a position to settle this issue with administrative finality, subject only to judicial review, there should no longer be any confusion with respect to the time at which safety and effectiveness data become available for public disclosure.

273. Comments argued that information concerning a drug on which a patent is pending should be considered prima facie confidential.

The Commissioner notes that a patent application may or may not be granted. A patent which has been granted may run out before the new drug status of a product is terminated. The Freedom of Information Act provides no special status for patented products, nor does the Federal Food, Drug, and Cosmetic Act. For these reasons, the patent status of a product cannot be relied upon by the Food and Drug Administration as determinative or indicative of whether information concerning that product should be released to the public.

274. Requests have been received for safety and effectiveness information with respect to a new drug for which an NDA is effective but which is currently subject to the drug efficacy study implementation (DESI) review program. Some of these data have been submitted after publication of an initial DESI notice but prior to a notice of opportunity for hearing, and some have been submitted in response to a notice of opportunity for hearing in order to justify a request for a hearing.

The Commissioner concludes that such data and information have the same status as any other data and information on safety and effectiveness contained in the NDA. Prior to final action revoking an NDA, requests for data and information will be handled in the same way as requests relating to any other approved NDA. If the NDA is withdrawn, after all appeals are exhausted the data and information will be disclosed in the same way that data and information are disclosed for all other NDA's for which approval is dented or withdrawn.

275. Questions have arisen as to whether an approval of an antibiotic drug for animal use is a private

license or a public regulation, and thus whether the safety and effectiveness data are or are not available for public disclosure upon such approval.

The Commissioner concludes that, although antibiotic drugs for animal use were formerly subject to the same form of approval contained in section 507 of the Federal Food, Drug, and Cosmetic Act as are antibiotic drugs for human use, i.e., a public regulation, the Animal Drug Amendments of 1968 (Pub. L. 90-399, 82 Stat. 342), which added section 512 to the act (21 U.S.C. 300b), changed this. Under section 512, all new animal drugs, including antibiotics, require an approved NADA, i.e., a private license, before they may lawfully be marketed. Accordingly, § 146.16 of the final regulations states the same disclosure rules for new antibiotic animal drugs as for any other new animal drugs.

276. Comments stated that, prior to the development of Form FD-1800, feed manufacturers had to submit essentially the same information as the animal drug manufacturer, in order to obtain approval for use of a new animal drug. It was the previous understanding that confidentiality of feed manufacturers' applications and related files would be honored. The comments stated that the Food and Drug Administration should honor this previous understanding.

The Commissioner advises that the Food and Drug Administration will honor the confidentiality of such applications insofar as the information contained in them is exempt under the Freedom of Information Act. In accordance with the provisions of
§ 4.45, any request for information contained in such applications will be discussed with the manufacturer if a close question is raised. The manufacturer will be given the opportunity to assert and justify confidential status for the material requested, and may appeal to the courts in the event the Food and Drug Administration determines that the material is disclosable.

277. Questions have been raised as to whether food additive and antibiotic petitions and forms for veterinary drugs submitted prior to the effective date of the Animal Drug Amendments of 1968 (Pub.L. 90-399, 82 Stat. 342) are subject to the disclosure rules established for these petitions and forms in §§ 121.51(h) and 431.71 or to the disclosure rules established for new animal drug applications in §§ 135.33a and 146.16. The Animal Drug Amendments changed the law by requiring approval of an individual new animal drug application for every new animal drug.

The Commissioner advises that the rules for disclosure will depend upon the nature of the approval requested or obtained. Accordingly, the food additive petitions and antibiotic forms submitted for animal drugs are subject to the disclosure rules established for these petitions and forms. The new drug applications submitted for veterinary drugs prior to the Animal Drug Amendments are similarly subject to the disclosure rules established in § 314.14.

278. Pursuant to the Controlled Substances Act (Pub. L. 91-513, 84 Stat. 1236), the Secretary of Health, Education, and Welfare is required to submit to the Attorney General a scientific and medical evaluation and recommendations relating to the scheduling of drugs. The preparation of such recommendations has been delegated to the Commissioner. Requests have been made for copies of such recommendations.

The Commissioner advises that all recommendations relating to the Controlled Substances Act are available for public disclosure.

A PROTOCOL FOR A TEST OR STUDY

279. A comment contended that the amount of money expended in developing a protocol should be irrelevant to its status as a trade secret, and that the only factors that should properly be considered in making this determination is whether it gives the owner an opportunity to obtain a competitive advantage and whether the protocol is in fact secret.

The Commissioner does not concur with this comment. Cost is one factor, but not the sole factor, in determining whether information constitutes a trade secret. However, the final regulations refer directly to the exemption for trade secrets and confidential commercial information in § 4.61, rather than attempt to specify all of the relevant factors involved.

280. Comments also contended that uniqueness is not necessary for a trade secret, and thus that this element should not be included in the criteria for determining whether a protocol constitutes a trade secret.

The Commissioner concludes that, if a protocol is not distinguishable in a significant respect from those developed by others, it cannot be regarded as providing a competitive advantage. Nevertheless, the regulations have been revised to refer only to § 4.61, rather than to attempt to set out the various criteria that will be use in determining when the standards set out in § 4.61 are met.

281. A comment stated that the criteria for determining the trade secret status of protocols seem to have eliminated the necessity of showing that a protocol is "used in one's business." It was suggested that the Restatement definition should apply, and that there must be a showing of commercial value. If protocols are not trade secrets or privileged or confidential commercial or financial information, they cannot be withheld under any other exemption.

The Commissioner advises that the criteria proposed in order to show that a protocol is a trade secret were intended to amplify the Restatement definition, not to replace it. The Restatement definition does apply to protocols, as well as to any other type of information for which trade secret status is claimed. The final regulations make this clear.

ADVERSE REACTION REPORTS, PRODUCT EXPERIENCE REPORTS, CONSUMER COMPLAINTS, AND OTHER SIMILAR DATA AND INFORMATION

282. The primary concern expressed in comments about release of this type of information was the possibility that it may frequently be "misinformation." It was pointed out that the occurrence of reaction "B" does not mean that "A" caused it, particularly in a situation where the person may have been consuming more than one product. It was further asserted that, when taken out of context, adverse reaction data are subject to misinterpretation, particularly by a layman unqualified to analyze them. As protection against misinterpretation, it was suggested that the

Food and Drug Administration not release any adverse reaction information until a scientific evaluation has been made of the reaction and its probable causation. Industry, it was asserted, had a right to expect this type of protection from "cranks and dissidents." Alternatively, it was suggested that release not be permitted until the firm involved agrees. It was also suggested that the manufacturer be given an opportunity to analyze reports by third parties, and reply to the agency before the reports are made public, in order to provide a fair and balanced disclosure.

The Commissioner rejects the presumption upon which the bulk of the criticism in the comments is based, i.e., that the public, scientists, and the Food and Drug Administration are incapable of making responsible judgments on this information. This type of information, when released, will be evaluated in the same manner as any other information that is publicly available.

283. Questions have arisen about the status of reports of adverse reactions to drug products subject to the requirements of the new drug or prescription drug sections of the law. Adverse reactions for new drugs are required to be reported to the Food and Drug Administration pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and adverse reactions for prescription drugs must be furnished to the Food and Drug Administration pursuant to the factory inspection provisions in section 704 of the act.

The Commissioner advises that such adverse reaction information is available for public disclosure with only the names and other identifying information of individuals deleted. The brand name of the product and the name of the manufacturer will not be deleted.

284. Questions have been raised as to whether adverse reactions reported to an IND file are available for public disclosure.

The Commissioner concludes that the same rules with respect to disclosure of adverse reactions should apply whether they are reported to an IND file or in a pending NDA. Such information is not available for public disclosure until the NDA is approved or finally disapproved or withdrawn, except that an individual who participates in a study involving an investigational new drug will be given a copy of any adverse reaction report relating to him. Such reports are required by law to be furnished to the Food and Drug Administration. The Commissioner concludes that furnishing adverse reaction reports under these limited circumstances raises no possible issue under the exemptions for privacy or trade secrets and confidential commercial information.

PRODUCT INGREDIENTS

285. Comments stated that even a simple list of ingredients in a product constitutes confidential commercial information which provides a competitive advantage, and that the exemption for a particular ingredient is not helpful because it may be a particular combination of all ingredients which makes the product unique and effective. It was suggested that a manufacturer be permitted to show that the entire list constitutes a trade secret.

The Commissioner rejects the suggestion that a list of ingredients is always confidential commercial information. To conform these regulations with the Drug Listing Act, however, they

have been revised to state that inactive ingredients in drug products not required to be stated on the label and not previously disclosed to the public are not available for public disclosure. The Commissioner also agrees that combination of ingredients as well as a single ingredient may qualify for exemption and the final regulations have been revised to reflect this.

286. One comment stated that this provision in the proposed regulation "is just another way of saying that excipient materials that are well known do not contribute significantly to the performance of the product." The choice of excipients, it was asserted, was arrived at by a considerable expenditure of funds and it was stated that, with the increasing attention paid to bioavailability, this process would becomes more costly. This regulation, it was concluded, would make it easier for generic drug manufacturers to arrive at superior products without having to conduct research and experience developmental delay. It was suggested that quantitative information be exempt except to the extent that it was disclosed on the label or labeling since the information required for public health already appears there, and that a manufacturer should not have to defend the confidentiality of any ingredient information by proving it unique.

The Commissioner agrees that undisclosed inactive ingredients in drugs will be handled as trade secret information.

287. A comment contended that an ingredient should be regarded as a trade secret if it provides a competitive advantage, and suggested that the criteria of uniqueness, importance to the product, and knowledge to competitors should be deleted.

The Commissioner intended the criteria set out in this provision of the proposed regulations to amplify the phrase "competitive advantage," and believes that they are an adequate reflection of the factors which comprise competitive advantage with respect to ingredients. Nevertheless the final regulations have been revised to refer directly to § 4.61 rather than to attempt to specify all of the criteria applicable in determining the status of an ingredient.

ASSAY METHOD OR OTHER ANALYTICAL METHOD

288. Comments contended that an essay method is a trade secret regardless whether it must be available to permit other manufacturers to comply with limits established under Food and Drug Administration regulations.

The Commissioner does not agree with these comments. For many years the Food and Drug Administration has routinely made available for public disclosure, and has included in its widely distributed manuals, analytical methods which are contained in petitions and applications, and which are needed for regulatory assays for food and drugs. The Association of Official Analytical Chemists (AOAC) publishes official analytical methods. Other methods are frequently published in the scientific literature. Accordingly, methods of this type are not customarily regarded as confidential information. Moreover, such methods are needed by State and local officials as well as by Federal officials to assure compliance with legal requirements. They provide no competitive advantage for one manufacturer over another, but rather permit regulatory officials to assure compliance with the law. Even if such methods were not made

publicly available to competing manufacturers, such competitors would still be permitted to market the products involved. Thus, the failure to make such methods public would deter only regulatory activity and would not hinder the marketing of competing products. Accordingly, the Commissioner concludes that all such methods will be made public except where they serve no regulatory function whatever. The final regulations have been revised to state this policy.

289. A comment indicated that it was not clear whether the Restatement definition of a trade secret must be met before assay methodology information will be retained as confidential. It was also stated that if the assay method is not required for the approval of a new drug, it does not provide a competitive advantage and therefore cannot be regarded as exempt.

The Commissioner advises that, as with any other information in the possession of the Food and Drug Administration which is to be exempt from disclosure as a trade secret, the information must be a trade secret within the meaning of the Restatement. The Food and Drug Administration has determined that assay methods are disclosable except where they perform no regulatory function and are shown to fall within the exemption established in § 4.61.

MANUFACTURING METHODS OR PROCESSES, INCLUDING QUALITY CONTROL PROCEDURES

290. Several comments noted that, although manufacturing methods and processes, quality control procedures, and quantitative formulas are specifically exempt from disclosure unless there has been a prior public disclosure, the proposed regulations also required all data to be market as confidential and adequate grounds given to justify each individual item so marked. Clarification of these seemingly conflicting provisions was requested.

The Commissioner advises that a company's manufacturing methods and processes, quality control procedures, and quantitative formulas are per se exempt from disclosure unless previously disclosed or later abandoned, and need not be marked as confidential or specially justified. A manufacturer need not submit a statement on prior public disclosure or subsequent abandonment unless so requested in a specific situation by the Food and Drug Administration.

291. The technical question was raised in comments as to whether adjuvants, such as catalysts or polymerization modifiers used in a secret manufacturing process for a polymer used as a food packaging material, would be available to the public.

The Commissioner concludes that, if the adjuvants are necessary to the manufacturing of a safe product, the food additive regulation itself must disclose their use. If they are not necessary for a safe product and are exempt from regulation as food additives but are described as part of the manufacturing process in a food additive petition on the final polymer, their use would not be disclosed to the public because, under § 121.51(h)(2)(i) of the final regulations, a manufacturing process is regarded as a trade secret that will not be disclosed.

PRODUCTION, SALES, DISTRIBUTION, AND SIMILAR DATA AND INFORMATION

292. No comments contended that production, sales, or distribution data and information should be available for public disclosure.

The Commissioner concludes that such information is per se exempt from public disclosure unless it is released in a blind compilation that does not disclose confidential information, and that it need not be marked as confidential or otherwise specially justified. The only form in which such information may be disclosed to the public is through a compilation which aggregates data from several sources, in a way that does not reveal the data from any particular source. This form of blind compilation of confidential commercial information is often prepared and made public by trade associations and the Department of Commerce.

293. Questions have been raised about the release of otherwise confidential commercial information, such as sales figures and manufacturing data, after a product has been withdrawn from the market and abandoned.

The Commissioner concludes that such information ordinarily no longer represents confidential commercial information or trade secret data once the product has been removed from the market and abandoned. It will be the Commissioner's practice to consult with the company involved before making a final decision on release of such information, however, to determine whether there are future plans for remarketing the product or whether the data in some way also disclose confidential information about other products that remain on the market.

294. One comment requested an amendment to the regulations to provide that the amounts and the identity of recipients of refunds from advance deposits of fees paid to the Food and Drug Administration for certification services constitute proprietary information, exempt from public disclosure.

The Commissioner concludes that such information is exempt from public disclosure only to the extent that it may disclose sales data or the share of individual companies in the market.

FOOD STANDARD TEMPORARY PERMITS

295. Questions have arisen about the availability for public disclosure of petitions received pursuant to § 10.5 of the regulations (21 CFR 10.5) requesting a temporary permit to vary from a standard of identity, or an extension of such a permit.

The Commissioner advises that all such petitions and related correspondence are available for public disclosure upon publication of the notice granting the permit in the FEDERAL REGISTER, except to the extent that these records contain information otherwise exempt from disclosure, e.g., manufacturing procedures or quantitative formulas. Prior to a notice in the FEDERAL REGISTER granting the petition, the existence of the petition is properly regarded as confidential commercial information, since it would disclose the intent of the company to pursue the marketing of a new product. Once such a notice is published, however, the petition can no longer be regarded as confidential. Similarly, a request for extension of the permit shall be

available for public disclosure if an extension permits other manufacturers to begin marketing under the same terms and conditions as the first manufacturer. A new paragraph (k) is added to § 10.5 to state this policy.

PROCESSING RECORDS FOR LOW-ACID CANNED FOODS

296. The Commissioner published in the FEDERAL REGISTER of May 14, 1973 (38 FR 12716) and subsequently amended in the FEDERAL REGISTERS of January 29, 1974 (39 FR 3750) and April 1, 1974 (39 FR 11876), new regulations governing emergency permit controls for thermally processed low-acid foods packaged in hermetically sealed containers (21 CFR 90.20). The final regulations require that manufacturers subject to these regulations furnish to the Food and Drug Administration various records relating to their processing. Questions have arisen with respect to the status of such records under the Freedom of Information Act.

The Commissioner advises that all such records constitute manufacturing or processing records that fall within the trade secret exemption from the Freedom of Information Act. In order to make this policy clear, a new paragraph (I) is added to § 90.20 in this final order.

COSMETIC PRODUCT INFORMATION

297. The Commissioner has promulgated regulations relating to voluntary registration of cosmetic product establishments, voluntary filing of cosmetic product ingredient and cosmetic raw material composition statements, and voluntary filing of cosmetic product experiences in the FEDERAL REGISTERS of April 11, 1972 (37 FR 7151) and October 17, 1973 (38 FR 28914). The recodification of cosmetic regulations under a new subchapter G--Cosmetics was published in the FEDERAL REGISTER of March 15, 1974 (39 FR 10054). Cosmetic manufacturers have informed the Food and Drug Administration that they have delayed the filing of ingredient and composition statements and product experience reports pending promulgation of final regulations under the Freedom of Information Act in order to determine whether such information, submitted voluntarily, will be retained as confidential by the Food and Drug Administration or will be disclosed to the public upon request.

Accordingly, the Commissioner concludes that clarification of these regulations at this time is appropriate in order to conform them with the provisions of Part 4.

298. Section 710.7 of the regulations (21 CFR 710.7) provides that a copy of Form FD-2511 (Registration of Cosmetic Product Establishment) is available for public inspection in its entirety.

It is the Commissioner's understanding that no question has been raised about the public disclosure of this document because it does not contain information relating to specific products. Accordingly, no modification in this provision is warranted.

299. Section 720.8 of the regulations (21 CFR 720.8) provides that Forms FD-2512 (Cosmetic

Product Ingredients Statement), and FD-2513 (Cosmetic Raw Material Composition Statement), and FD-2514 (Discontinuance of Commercial Distribution of Cosmetic Product or Cosmetic Raw Material), and amendments thereto, must be clearly marked as confidential if trade secrets status is claimed. The provision states that, if the Food and Drug Administration concludes that an item so marked is not exempt from disclosure, the matter may be appealed within the agency for a final decision.

The Commissioner concludes that § 720.8 should be revised to make it consistent with the general provisions contained in new Part 4 as promulgated by these final regulations. The Commissioner further concludes that, by incorporating the procedural safeguards contained in new § 4.44 and clarifying the status of voluntary ingredient disclosures in § 4.111, and adopting the principles for disclosure enunciated in the other provisions of Part 4, any questions about the status of the information contained in these forms will be resolved.

300. Section 730.7of the regulations (21 CFR 730.7) provides that Forms FD-2704 (Cosmetic Product Experience Report), FD-2705 (Cosmetic Product Unusual Experience Report), and FD-2706 (Summary Report of Product Experience by Product Categories) Shall be handled in accordance with the final regulations to be published by the agency under the Freedom of Information Act.

The Commissioner is therefore also amending § 730.7 to include the rules laid down in the final regulations established in Part 4. The Commissioner concludes that these rules will adequately protect against unfair disclosure of materials regarded by the industry as constituting important confidential commercial information and at the same time assure that information that is of major importance to Food and Drug Administration regulatory programs will in fact be submitted.

301. Questions have arisen as to the procedure by which a person who has submitted a request for confidentiality of cosmetic ingredient information pursuant to Part 720 may appeal a decision by the Bureau of Foods that the information does not constitute a trade secret and thus is available for public disclosure pursuant to the Freedom of Information Act.

The Commissioner concludes that the procedure established in new § 4.44 is properly used to resolve any issues of this nature, prior to submission of the information involved. Since this determination controls the question whether the ingredient(s) involved must be labeled pursuant to § 701.3 (21 CFR 701.3), which was published in the FEDERAL REGISTER of October 17, 1973 (38 FR 28912), an adverse determination constitutes final agency action that may be challenged in the courts. Section 720.8 is revised to reflect these conclusions.

The Commissioner realizes that a number of cosmetic companies have already submitted ingredient information with a request for confidentiality pursuant to Part 720. In order to deal fairly with all of these submissions, the Commissioner has concluded that all such requests for confidentiality will now be handled pursuant to the procedure established in new § 4.44. In the event that it is determined that the information involved is not confidential, the company will have the opportunity to withdraw the information or to submit it without a pledge of confidentiality. This will place those manufacturers who have already submitted this information

to the Food and Drug Administration on an equal footing with those who have delayed such submission until the procedures for review of confidentiality were clarified.

BIOLOGICAL DRUGS

302. Subsequent to publication of the proposed regulations in May 1972, jurisdiction over section 351 of the Public Health Service Act (42 U.S.C. 262), which governs the licensing of biologics, was transferred to the Food and Drug Administration. Under section 351, a biologic must be licensed by the Food and Drug Administration before it may lawfully be shipped in interstate commerce. Unlike the regulation of human and animal drugs, all biological products are required to undergo clinical testing in order to demonstrate safety, purity, potency, and effectiveness prior to licensing, regardless whether other versions of the same product are already marketed or standards for the product have been adopted by rule making. Indeed, many of the existing standards require specific clinical testing before approval will be granted. This is required because all biological products are to some extent different and thus each must be separately proved safe, pure, potent, and effective. Although, like an approved NDA, a license to manufacture a particular biologic is a private license that is applicable only to a single manufacturer, a biologics license is under no circumstances granted by the Food and Drug Administration to a second manufacturer based upon published or otherwise publicly available data and information on another manufacturer's version of the same product. Under section 351 of the Public Health Service Act, biologics never become "old drugs" and cannot be marketed solely on the basis of an existing product standard published in the FEDERAL REGISTER. There is no such thing as a "me-too" biologic.

Thus, the regulatory scheme for biologics is quite different from the methods by which new drugs and antibiotic drugs are controlled under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and 357).

Accordingly, the Commissioner concludes that the safety and effectiveness data for a biologic regulated under section 351 of the Public Health Service Act is not properly classified as a trade secret. Such data afford no competitive advantage because, unlike the situation with new drugs, no competitor can utilize it to gain approval for his product. Moreover, since such data are routinely published in the scientific literature, they do not fall within the confidential commercial information exemption. New §§ 601.7 and 601.8 are added to the existing regulations for biologics to state this policy.

303. During the past 2 years, requests have been made for various types of information contained in Food and Drug Administration files relating to approval of particular lots of a biologic.

The Commissioner concludes that all forms used within the Bureau of Biologics to show what testing has been undertaken by the Bureau on a particular lot, the results obtained, and whether approval was granted, are available for public disclosure. All documents showing the manufacturer's testing of a particular lot will also be released, except to extent that it would show the volume of the drug produced, manufacturing procedures and controls, yield from raw

materials, costs, or other similar confidential commercial information. New § 601.8 reflects this policy.

FEDERAL HAZARDOUS SUBSTANCES ACT

304. Jurisdiction over the Federal Hazardous Substances Act has been transferred to the Consumer Product Safety Commission pursuant to the Consumer Product Safety Act. (Pub. L. 92-573, 86 Stat. 1207; U.S.C. 2051 note), as published in the FEDERAL REGISTER of September 27, 1973 (38 FR 27012).

Accordingly, the proposed amendment of § 191.213 (21 CFR 191.213) is withdrawn.

RELIANCE UPON FOOD AND DRUG ADMINISTRATION FREEDOM OF INFORMATION FILES

305. In preparing the final regulations, the Commissioner has relied both upon the extensive comments filed on the proposed regulations published in May 1972, and upon the numerous requests for documents received by the agency since enactment of the Freedom of Information Act. Accordingly, the Commissioner hereby incorporates by reference the Freedom of Information files of the agency as part of the administrative record on which the decision on these final regulations is based.

ADDITIONAL TIME FOR COMMENT

306. The final regulations promulgated in this final order reflect both the proposal published in May 1972 and the actual practice of the Food and Drug Administration in handling requests for documents in the intervening 2 years. Comments submitted on the proposal and requests for documents during the past 2 years have raised most of the issues discussed in this preamble and resolved in the final regulations. Accordingly, these regulations embody very few new decisions.

The Freedom of Information Act is a self-executing statute for which no regulations are required for implementation. The Food and Drug Administration is therefore obligated to disclose documents not specifically exempt from disclosure regardless of the existence of published rules of the type promulgated in this final order.

Accordingly, the Commissioner concludes that these regulations will become effective 30 days after publication in the FEDERAL REGISTER.

Nevertheless, the Commissioner recognizes that it has been over 2 years since these regulations were first proposed, that the final regulations incorporate some new decisions not specifically dealt with in the proposal or the comments, and that sound public policy supports allowing time for comment wherever feasible. Accordingly, the Commissioner is providing an additional 60 days within which to present further brief comments on issues not raised by the initial comments and discussed in this preamble. The Commissioner will then rule on those comments very expeditiously and will publish an additional order ruling upon any such matters.

The Commissioner advises that comments submitted within this additional period should address new issues, and should not reopen matters raised by the initial proposal and fully discussed in this preamble. The Commissioner is particularly interested, for example, in any comments on the new portions of the procedural regulations contained in Subpart B of Part 4 and on the new provisions relating to biological drugs, as well as on any other similar provisions which were not covered in the proposal and the comments received on it.

The Commissioner concludes that the entire final order will become effective (*insert date 30 days after date of publication in the* FEDERAL REGISTER) and that all of the provisions will be implemented pending reconsideration of any specific provisions as a result of the receipt of additional comments. This will work no hardship since, if any close or controversial issues arise, the Commissioner will utilize the provisions of § 4.45 to consult with any person who may be adversely affected by disclosure of information, and that person will have the opportunity, as set forth in § 4.46, to seek judicial determination on the issue of disclosure in the event that he disagrees with the Commissioner's conclusion.

JUDICIAL REVIEW OF FINAL REGULATIONS

307. The Commissioner notes that one of the major purposes of the initial proposal published in May 1972 and these final regulations is to settle the status under the Freedom of Information Act of every category of document contained in Food and Drug Administration files, in order to avoid ad hoc decisions and to facilitate prompt handling of requests for records.

The comments disclose a wide divergence of opinion with respect to the rules contained in these final regulations. Some comments stated that far too much was being released, and others stated that not enough was being released. The Commissioner anticipates that the same disagreement will exist with respect to portions of the final regulations as was reflected in the comments received on the proposal.

Accordingly, the Commissioner invites any person who believes that the final regulations do not properly interpret and apply the Freedom of Information Act to institute legal action in the courts to contest their validity. The Commissioner concludes that, after receipt of the additional comments permitted and any further modifications as a result thereof, all administrative remedies with respect to these matters will be exhausted, that the matters will be ripe for judicial review, and that any person will have standing to bring suit to contest these regulations since they affect the rights of the entire public, including those who have submitted or will submit information to the Food and Drug Administration and those who have requested or will request disclosure of such information by the Food and Drug Administration. The Commissioner believes that it would be in the public interest for all such issues to be litigated promptly so that these matters may be settled and the applicable rules clearly understood by everyone who is affected.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 et seq. as amended; 21 U.S.C. 321 etc seq.), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682 et seq. as amended; 42 U.S.C. 201 et seq.), and the Freedom of

Information Act (Public Law 90-23, 81 Stat. 54-56 as amended by 88 stat. 1561-1565; 5 U.S.C. 552) and authority delegated to the Commissioner (21 CFR 2.120), Parts 1, 2, 4, 8, 10, 90, 121, 135, 146, 312, 314, 431, 601, 720, and 730 are amended follows:

Title 21-Food and Drugs

CHAPTER 1-FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
[Docket No 76N-0067]

The Food and Drug Administration (FDA) is issuing a second final regulation concerning public information in response to comments on the initial promulgation of such regulations. This final order does not change most of the agency's current regulations, either because no comments were received or because the comments submitted did not persuade the Commissioner of Food and drugs that changes were in order. Certain provisions are being revised, however, to make it clear that the agency will not ordinarily provide more than one copy of a record to the same person, to clarify the agency's policy respecting waiver of fees, and to effect other changes. This order shall be effective February 14, 1977.

In the FEDERAL REGISTER of December 24, 1974 (39 FR 44602), the Commissioner of the Food and Drugs issued final regulations governing the disclosure of information to the public in conformity with the public information section of the Administrative Procedure Act, known commonly as the Freedom of Information Act (FOIA) (5U.S.C. 552). Interested persons were invited to file, within 60 days of publication of the final order in the FEDERAL REGISTER, written comments regarding matters not raised in the notice of proposed rule making published in the FEDERAL REGISTER of May 5, 1972 (37 FR 9128, and considered in the preamble to the final regulation. The final regulation provided that any changes justified by the comments would be the subject of further regulation amending the specific regulations involved.

The Commissioner received 28 comments; the majority repeated substantive comments previously made on one or more sections of the original proposal, although some dealt with matters not previously raised and considered. The majority of the responses, mainly from trade associations and representatives of companies subject to regulation under the laws administered by FDA, objected to specific provisions of the final regulation, and suggested changes that would make less information in government files available for public disclosure. The few comments received from individuals and consumer groups generally supported the provisions of the final regulation, and suggested changes to further liberalize agency disclosure policies. Those letters making new substantive comments or suggestions and Commissioner's conclusions concerning them are discussed in this preamble. The respondents that raised matters that were previously considered in the preamble to the December 24, 1974 final regulation, and references to the specific paragraphs of that preamble wherein they were considered, are also briefly set out below. For the convenience of the reader, wherever this preamble are grouped under the appropriate headings of the preamble to the December 24, 1974 final regulation.

FDA EXPERIENCE UNDER THE FREEDOM OF INFORMATION ACT

1. In the preamble to the December 24, 1974 final regulation, the Commissioner noted that the May 1972 proposal represented a major change from prior agency policy. Before the regulations were proposed, the agency retained approximately 90 percent of its records as confidential; since the May 1972 proposal, approximately 90 percent of FDA records have been available for public

disclosure. The Commissioner concluded in the preamble to the December 24, 1974 final regulation that the impact of this policy change on FDA was beneficial rather than detrimental. The policy of open disclosure, the Commissioner concluded, impeded neither communication with persons outside the Federal government nor internal agency deliberations, but had the salutary effect of encouraging closer public scrutiny of FDA actions and "fostered greater public accountability of the agency." The beneficial effects of the FDA openness policy, reflected only in part in its public information regulations, caused the Commissioner to enlarge the categories of documents available to the public by his conclusion in the preamble to commit the agency to liberal use of its discretion under FOIA to disclose records that could be withheld from the pubic under strict terms of the act's nine exemptions.

Since publication of the final regulations in December 1974, FDA experience confirms the Commissioner's conclusion that a policy of open disclosure is in the best interests of the public and the government. Remaining fully committed to this policy , FDA will continue to strive to meet both the spirit and letter of the FOIA. Although the FOIA and these regulations have generally resulted in substantial public benefits, they have also produced some unexpected and, for the agency, disappointing consequences. The volume of freedom-of-information (FOI) requests received by FDA has been much larger than anticipated. During fiscal year 1975, FDA received approximately 5,300 request; in fiscal year 1976, the total number of requests ballooned to nearly 20,000. This trend continues today and the Commissioner expects that FDA will receive over 24,000 requests in fiscal year 1977. A large proportion of the requests received by FDA are lengthy, voluminous and complex, which makes responding to them involved, time consuming, and costly. Last year, FDA's uncompensated cost of responding to FOI requests exceeded $1 million. Fees charged, which are supposed to reflect actual cost to the government totaled only $78,340. This disparity between the cost to FDA and the revenue from fees is disturbing because 86 percent of the FOI requests received by FDA are from industry and private attorneys, while only 15 percent come from the general public consumers, press, health professionals, and scientists. It is, in the Commissioner's view inappropriate that the general public must subsidize the "industrial espionage" in which many commercial firms engage.

The Commissioner does not intend to modify the FDA disclosure policy because of "imbalance" in requests. However, the Commissioner does intend to take steps to secure a revision in the fee schedule to more closely reflect the actual cost incurred by FDA in searching for requested documents. The Commissioner's views concerning the fee schedule are fully set forth elsewhere in this preamble; namely, an increase in the fee schedule coupled with a more liberal application of agency policy on waiver of fees will result in a more equitable distribution of the costs of responding to FOI requests without affecting the amount or type of records available to the public.

PROCEDUREAL ISSUES REALTED TO PROMULGATION OF FINAL ORDER

2. Many comments contended that the promulgation of the final regulation December 1974 represented a novel concept in agency rule making not in accordance with the notice and comment requirements of section 4 of the Administrative Procedure Act. It was asserted that the regulations are more than a mere particularization of the FOIA, and reflect FDA interpretation of the provisions of the act and their applicability to specific categories of documents in the FDA files. It was argued that, because the final regulation differs in numerous and substantial respects from the

May 1972 proposal, these regulations should be treated as entirely new and published as a proposal with a full comment period before their issuance in final form. It was further asserted that the justification in the preamble for the procedure used by FDA, i.e., that the FOIA is self-executing, even if assumed to be a correct statement, is not dispositive of the procedural objections. Comments noted that the
preamble and regulations endeavor to interpret and reconcile seemingly conflicting statutes and to make substantive determinations as to what constitutes trade secrets and confidential commercial or information. These interpretations, reconciliations, and determinations were said to be of such significance and were such a substantial departure from past practice that they cannot be viewed as merely the implementation of a self-executing statute.

The Commissioner does not agree with these comments. The FOI regulations were promulgated in accordance with 5 U.S.C. 552(a)(1), to apprise the public of how FDA intended to respond to the congressional mandate. The issuance of these detailed regulations also enables persons, in advance of disclosure, to determine whether documents that they previously submitted to FDA and believe to be confidential fall into a disclosable category and to seek immediate judicial review if they disagree with the classifications of the agency. Many agencies, in implementing the FOIA, have issued regulations without affording any time for public comment. Others have issued regulations that merely parallel the language of the statute, providing no more guidance as to the **disclosibility** of certain records that the FOIA itself. In contrast, FDA published in the FEDERAL REGISTER a notice of proposed rule making with a 60-day comment period. That proposal and the subsequent final regulation contained a detailed statement of how categories of records in the files of the agency were to be treated. The Commissioner concludes that the procedures followed more than met the requirements of any provision of the Administrative Procedure Act and were not legally defective in any respect.

Moreover, a 60-day comment period was provided after the promulgation of the final regulation to enable persons to comment further on issues not previously raised. The comments received during that 60-day period are the subject of this preamble and final regulation. Any asserted error failing to issue the December 1974 publication as a proposal was therefore corrected by providing this additional time for comment. Thus, the Commissioner is confident that the procedures followed in promulgating these regulations have full satisfied all applicable procedural requirements.

3. Comments also asserted that the request in the preamble to the December 24, 1974 final regulation that "comments submitted within this additional period should address new issues and should not reopen matters raised by the initial proposal and fully discussed in this preamble" makes it impossible to delineate those portions of the final regulation deemed proper for comment and that a rule making procedure that restricts comments to unspecified portions of the regulations and preamble is procedurally defective.

The Commissioner concludes that there is nothing improper about requesting comments on new matters and discouraging those raised by the initial proposal and fully discussed in the preamble to the December 24, 1974 final regulation. To determine whether a matter had been previously raised and discussed, persons merely had to refer to that preamble. If the matter they desired to comment upon was not the subject of earlier comment and was not discussed in the preamble, it was

appropriate to submit a comment upon it.

Moreover, many comments ignored the Commissioner's request quoted above and commented upon matters raised and fully discussed previously, sometimes in language identical to that used in earlier comments. Nonetheless, these comments have been reviewed by the Commissioner and, in most instances, they are briefly discussed in this preamble. The Commissioner therefore concludes that no person was constrained from making any comment on any portion of the final regulation.

4. Comments contended that, to the extent that the lengthy preamble is deemed by FDA to have the effect of a legal advisory opinion or to modify, limit, or expand the meaning of the regulations, the preamble constitutes rule making subject to the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553). The Commissioner does not agree with these comments. The preamole is intended to explain the regulations and has the status of an advisory opinion. It does not modify, limit, or expand the meaning of the regulations. The preamble is a discussion of specific situations expected to arise involving the application and interpretation of the regulations. The preamble, accordingly, merely sets forth the Commissioner's interpretation of the regulations as applied in specific situations, and thus does not constitute rule making subject to the notice and comment requirements of the Administrative Procedure Act.

5. A few comments contended that the determination of disclosability is not amendable to quasi-legislative treatment by regulation according to category or type of record. It was argued that each determination involves the exercise of the adjudicative function of the agency and must be evaluated on its own merits in a proceeding according not only notice, but opportunity for hearing and the presentation of comment by persons who might be affected by disclosure.

The Commissioner advises that the requirements imposed by this comment before agency disclosure of any record within its files are inconsistent with the mandate of the FOIA and would frustrate the implementation of that act by the agency. This point has been recognized by the United States District Court for the District of Columbia in Pharmaceutical Manufacturers Association v. Weinberger, 401 F. Supp. 444, (D.D.C. 1975), subsequent opinion, 411 f. Supp. 576, 579 (D.D.C. 1976), where the court noted. Broad, categorical regulations are therefore imperative. Ad hoc inquiries or item by item consultations would not only be impractical but also undercut the open disclosure policy of the FOIA and the FDA
regulations.

The Commissioner therefore rejects this comment.

6. Comments contended that the final regulation of December 24, 1974, does not comply with Executive Order 11821, issued November 27, 1974, requiring a statement certifying that the inflationary impact of all major legislative proposals impact of all major legislative proposals, regulations, and rules emanating from the executive branch of the Federal Government has been considered.

The Commissioner notes that FDA is required by law to implement the FOIA, a fact not altered by the Executive Order. These regulations are intended to implement the act and to provide guidance on the manner in which various types of documents will be handled by the agency. Records available under a specific section of the regulations. Accordingly, the Commissioner concludes that Executive Order 11821 is not applicable to these public information regulations. Moreover, the Commissioner is unable to discern, nor did any comments identify, any inflationary impact that these regulations could have.

SECTION 305 HEARING RECORDS

7. Several comments objected to the availability for public disclosure of information contained in the file relating to a section 305 hearing (an informal hearing held prior to institution of criminal proceedings, provided for by (section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) after the file is closed or the statute of limitations has run, whichever occurs first. The comments objected sharply to the availability for public disclosure of records pertaining to an individual considered for prosecution, but not prosecuted, and to the release of company and product names. It was argued that no useful regulatory purpose would be served by such disclosures, and that disclosure of company and product names may deprive persons of their right to a fair trial in matters not involving FDA. The assertion was also repeated that disclosure of company and product names would subject the company to an "onslaught of adverse publicity." Comments also asserted that the release of section 305 hearing records constitutes an unwarranted invasion of privacy.

The Commissioner has, in paragraph 16 of the preamble tot he December 24, 1974 final regulation previously concluded that Congress has determined that the right of the public to this type of information in government files outweighs any potential harm caused by the release of such information. It is only through the release of section 305 hearing records after the matter is closed that the exercise of prosecutorial discretion by FDA and the Department of Justice may be subject to scrutiny and public accountability. This is particularly true when prosecution is not recommended or is recommended but not instituted. Furthermore, the names and other information that would identify individuals are deleted before disclosure except when the Commissioner concludes that there is a compelling public interest in the disclosure of the names. The privacy rights of individuals will, accordingly, be protected.

The Commissioner concludes that the possibility that the release of section 305 hearing records will interfere with any person's right to a fair trial or impartial adjudication in matters not involving FDA is too remote and speculative to justify nondisclosure of those records. Finally, the possibility of adverse publicity stemming from the release of records such as section 305 hearing records without the deletion of company or product names was considered by Congress and, absent any provision in the FOIA for the deletion of such names, must be deemed to be outweighed, in the judgment of Congress, by the public's right to the information. The Commissioner has previously concluded that the protection of privacy afforded by the Constitution and the six exemption of the FOIA (5 U.S.C. 552 (b)(6)) extends only to individuals. The recently enacted Privacy Act (5 U.S.C. 552a) also protects only the privacy rights of the individuals.

8. A seeming anomaly was also noted, in that paragraph 18 of the preamble to the December 24, 1974 final regulation provides that if records relating to a closed section 305 hearing for a specific individual are requested by name, they will be released only after deletion of names and any information that would identify the individual. The Commissioner advises that the names and identifying details are deleted from section 305 hearing records requested by name to protect against indiscriminate subsequent disclosures. The requesting party obviously knows the name of the person, but deletion minimizes the possibility of additional widespread publicity. Accordingly, section 305 hearing records will be released only after the names and identifying information are deleted.

9. Several comments objected to the provision in õ 1.6(c) (4) (21 CFR 1.6(c)(4) for the release of section 305 hearing records respecting possible criminal prosecution of individuals without deleting the names and identifying information when the Commissioner determines that there is a "compelling public interest" to do so. The contention was made that such discretionary disclosure exceeds the authority of the Commissioner under the FOIA and, without guidelines for such discretionary disclosure, the release of section 305 hearing records relating to possible criminal action without deleting the names and identifying information would be unreasonable and arbitrary. One comment suggested that the written consent of the individual who was the subject of the investigation be obtained before the release of any names or identifying information.

The Commissioner advises that disclosure of section 305 hearing records respecting possible criminal prosecution with the names and identifying details intact may, depending on the particular circumstances, be completely consistent with the FOIA and the Privacy Act. If the public's interest in disclosure is indeed "compelling," the benefits in disclosure outweigh any infringement of personal privacy. In applying 5 U.S.C. 552 (b) (6), the courts have required that the benefits from disclosure be weighed against any possible infringement of personal privacy. The determination that a "compelling public interest" exists that warrants release of the names and identifying information pertaining to individuals considered for prosecution will be made in accordance with traditional criteria for such determinations, and after due consideration of those factors listed in õ 4.82 (21 CFR 4.82) of the final regulation.

The Commissioner rejects the suggestion that the written consent of the individual who was the subject of the investigation be obtained before the release of names or identifying information. The ultimate responsibility for compliance with the FOIA by FDA rests with the Commissioner. There is no requirement in the FOIA that the consent of individuals be obtained before the release of disclosable information. When the Commissioner concludes that there is a compelling public interest warranting release of names or identifying information, the records will be released without deletions whether or not consent is given by the individual who was the subject of the investigation.

OFFICIAL RECORDS AND INFORMATION

10. Questions have arisen as to whether the phrase, "testimony before any tribunal," as used in õ 4.1(a) (21 CFR 4.1(a) of the final regulations includes committees of Congress.

The Commissioner advises that õ4.1 was first published in the FEDERAL REGISTER of December 20, 1955 (20 FR 9554). It was designed to prevent the subpoena of agency officials in private litigation and similar matters. The phrase "testimony before any tribunal" has not been, is not intended to be, and will not be interpreted to be, and will not be interpreted to include committees or subcommittees of Congress.

11. One comment contended that FDA employees should be free to give testimony without first securing the permission of the Commissioner because the public is entitled to information from FDA employees which is not filtered through the Commissioner.

The Commissioner regards this suggestion as impractical and contrary to the public interest. The Food and Drug Administration now receives a very large number of requests for agency employees to testify in private litigation and other matters in which FDA is not a party. Were agency employees free, or required, to testify in private litigation whenever requested, the regulatory activities could be severely disrupted. The agency could not adequately function if its 6,500 employees were constantly preparing for and giving testimony in private litigation. Section 4.1 is therefore necessary for the agency to fulfill its primary regulatory responsibilities.

UNIFORM ACCESS TO RECORDS

12. One comment requested that disclosure of experience reports submitted by physicians and hospitals be restricted to health care professionals and institutions on the grounds that the general public does not possess sufficient expertise to interpret the significance of such reports and that release, upon request, to any member of the public would result in undue public alarm and unjustified concern by individuals under medication.

The Commissioner has previously advised, in paragraph 31 of the preamble to the December 1974 final regulation, that, if any information is available to one member of the public, it must available to all. Under the FOIA, the disclosure of information does not depend ordinarily on the requestor's interest in or ability to understand the information sought.

PARTIAL DISCLOSURE OF RECORDS

13. A comment suggested that, whenever FDA determines that a document contains both disclosable and nondisclosable material, the agency should consult with the submitter of the document before any release to determine the extent to which the disclosable material may be segregated from the nondisclosable. It was argued that consultation is especially necessary when the requested document is technical because the expertise necessary to identify nondisclosable

material is likely to be possessed only by the submitter.

The Commissioner concludes, and has previously stated, that the submitting person, and possibly other affected persons, will be consulted only if there exists a close question of the confidentiality of the requested records. If a close question exists, because of the intermingling of disclosable and non disclosable information, be it technical or otherwise, consultation will occur. The mere fact that disclosable and nondisclosable information is contained in a single document, as is often the case, does not warrant automatic consultation. If the information cannot be reasonably separated from the nondisclosable information by FDA without the benefit of additional information, this would constitute a close question.

14. Several comments asserted that the application of these application of these regulations to material in FDA files submitted in confidence before the effective date of the final regulation is a retroactive application of the regulations that constitutes a denial of administrative due process to the submitter of such material unless notice is given to the submitter in advance of public disclosure of a particular item.

The Commissioner advises that Congress intended in enacting the FOIA to reverse the disclosure policies of Federal agencies to make disclosure the rule and nondisclosure the exception. Congress did not distinguish between information submitted before the FOIA was passed and that submitted after passage. Furthermore, information that is not otherwise exempt under one of the nine exemptions of FOIA cannot be made exempt on the basis of a "pledge of confidentiality." Petkas v. Staats, 501 F. 2d 87, 889 (D.C. Cir. 1974; Charles River Park A Inc. v. HUD, 519 F. 2d 35, (D.C.Cir. 1975). The application of the final regulations to all records in FDA files, regardless of when submitted, has been squarely upheld in Pharmaceutical Manufacturers Association v. Weinberger, 411 F. Supp. 576, 580 (D.D.C. 1976). The question of notice to the submitter before disclosure was also an issue in that case is discussed in paragraph 37 below.

The Commissioner does not agree with this comment. Neither the FOIA nor the Federal Food, Drug, and Cosmetic Act contains provisions similar to section 6 (b)(1) of the Consumer Product Safety Act. To the extent that section 6(b)(1) can be said to require notice to submitting persons and persons who might be affected by disclosure, its provisions are not applicable to FDA. 42.

One comment pointed to the notice provisions of the public information regulations of the environmental Protection Agency (40 CFR 2.105 (b) and 2.107 (a)) as a model for FDA follow.

The Commissioner concludes that the notice provisions of the public information regulations of the Environmental Protection Agency are not required by the FOIA, and, given the number of requests received by the FDA, adoption of a similar notice provision would be an unmanageable administrative burden that would impair the ability of the agency to adhere to the 10-day requirement for ruling on requests as mandated by the 1974 amendments tot he FOIA and to carry out its important regulatory functions.

43. One comment requested that whenever FDA discloses records to special government employees under 21 CFR 4.84, other Federal departments or agencies under 21 CFR 4.85, State and local government officials under 21 CFR 4.88, and officials of foreign governments under 21 CFR 4.89 the person who submitted the information to the FDA be give notice consisting of the date, actual content, and person to whom the disclosure was made.

The Commissioner advises that all the classes of persons referred to the comment have a special status entitling them to the information, and they are prohibited from releasing data and information that is exempt from disclosure, such as trade secrets, in the same fashion and the extent as all employees of FDA. No purpose would be served by providing notice of the sort requested when disclosures are made in accordance with the regulations to persons in those categories.

44. Another comment asserted that under no circumstances should notice to affected persons be given because such notice permits the submitter to attempt to persuade FDA that the request should be denied, and the requestor has no similar opportunity to persuade the agency that the request should be granted.

The Commissioner does not agree with the position expressed in this comment. On the limited occasions when the confidentiality of a requested record is uncertain, consultation with the submitting person or persons to obtain additional information related to the status of the record is essential if a proper determination is to be made by FDA. Consultation under õ 4.45 (21 CFR 4.45) is not an opportunity for affected persons to persuade the agency, by argument alone, not to release the requested material. It is, rather, an opportunity for the agency to examine and consider additional data and information not otherwise available to it, which will be of assistance in making a correct determination respecting the confidentiality of the requested record

JUDICIAL REVIEW OF PROPOSED DISCLOSURE

45. A number of comments stated that the 5 days provided in õ 4.46 (21 CFR 4.46) within which to institute suit to enjoin the release of records is an inadequate period of time for affected persons to make the decision to seek an injunction and to prepare and file the appropriate pleadings. It was variously suggested that 10, 15, or 20 days, or 10 working days, be provided within which to institute suit. One comment suggested 5 days be provided to notify FDA of the intent to sue and an additional 90 days within which to institute suit. If no court suit was initiated after 90 days, the comment suggested, FDA could then release the material.

46. One comment objected to any time period for the institution of suit to enjoin the release of records and argued that once FDA determines to disclose records, those records should be made available immediately to the requesting party.

The Commissioner regards the provision of a limited time period for the institution of suit to enjoin the release of records when confidentiality is uncertain and FDA has determined to release the records as reasonable and consistent with the provisions of the FOIA and its mandate.

DENIAL OF REQUEST FOR RECORDS

47. Questions have arisen about the circumstances in which FDA will, under õ 4.47(d) (21 CFR 4.47(d)), delete certain information from requested records without treating the deletions as a denial of the request. Concern has been expressed that person making a request for records who subsequently receive records with certain information deleted may not always realize that deletions have been made or that they may appeal those deletions to the Assistant Secretary for Health, Department of Health, Education and Welfare.

The Commissioner advises that it has been the consistent policy of FDA to treat substantial deletions of material from a record that is nevertheless disclosed as a denial and FDA had according informed the person who made the request of his appeal rights. In order that there be no question about this policy, õ 4.47(d) is revised to apply explicitly only to minor deletions of nondisclosable data and information from otherwise disclosable records.

The Commissioner further advises that the agency's policy with respect to minor deletions of nondisclosable data and information from disclosable records is to identify clearly such deletions on the record that is disclosed, but not to view such minor deletions as a withholding of the requested record. This policy is premised on three considerations. The majority of records in the files of FDA are disclosable to the public under the regulations. However, a large number of these clearly disposable records do contain small items of data and information that under the FOIA exemptions and the regulations, are exempt from disclosure. Deletions are, therefore, common.

For example, FDA receives many requests for adverse drug reaction reports that are submitted to the agency by physicians, hospitals, and drug manufacturers. In many cases, these reports contain the name and address of the patient who incurred the adverse reaction as well as the name and address of the physician or institution submitting the report. In order to protect the personal privacy of such persons, it is standard practice to delete the name and address as well as any other identifying details from adverse reaction reports. This policy is clearly stated in §§ 4.63 and 4.11 (21 CFR 4.63 and 4.111) and is unquestionably consistent with the sixth exemption of the FOIA (5 U.S.C. 552 (b)(6). Deletions of this sort, minor in nature, ubiquitous, and clearly authorized by the FOIA, the regulations of HEW that implement the act (45 CFR 5.71(a) and these regulations (§§ 4.63 and 4.111) have not been treated by the agency as denials. Furthermore, in the Commissioner's view persons making requests to FDA for records ordinarily fully expect that minor deletions will, of necessity, be made and that their requests do not encompass the types of data and information that are regularly deleted before disclosure. This is particularly so because a large number of FOI requests received by the agency are from persons who frequently make such requests and who are, no doubt, familiar with the agency's public information regulations and practices. Finally, under
the 1974 amendments to the FOIA, agencies are required to disclose "[a]ny reasonably segregable portion of a record" after deleting exempt portions (5 U.S.C. 552(b)). It would be anomalous if Congress intended this amendment to result in denials of requests. It was obviously the intent of

Congress that more disclosures would result, not more denials. In view of these considerations, the Commissioner believes that the agency's policy regarding minor deletions is consistent with the FOIA. Nevertheless, to assure that all persons who request records from FDA fully understand the policy of the agency regarding minor deletions, the Commissioner has recently instituted a policy of including in every letter of determination issued by the agency granting a request for records that, when disclosed, will contain minor deletions, a paragraph that (a) calls attention to the deletions; (b) states that the agency assumes that the deleted material was not intended to be covered by the request; (c) indicates that if the agency's assumption is erroneous, the person making the request should advise the agency that he or she does indeed desire to receive the deleted material; and (d) states that if the agency should then deny the requested additional information, a letter would issue that fully explains the appeal rights and procedure available to the person making the request. The Commissioner is confident that this policy will preclude any misunderstanding by persons requesting records from the agency when the records that are disclosed contain minor deletions.

USE OF PRIVATE CONTRACTOR FOR COPYING

48. A few comments requested that õ4.51 (21 CFR 4.51) be revised to provide that a private contractor will not be used for copying when a records contains disclosable and nondisclosable material unless the contractor agrees in writing not to disclose the material to anyone and adequate precautions are taken by FDA to guard against the loss of or failure to return records loaned for copying purposes.

The Commissioner concludes that the recommendation is unnecessary. Ordinarily records containing nondisclosable material will not be provided to a private contractor for copying. In the rare circumstance that this might occur, the safeguards suggested in the comment would be established as a matter of course.

INDEXING TRADE SECRET AND CONFIDENTIAL COMMERICAL OR FINANCIAL DATA AND INFORMATION

49. A number of comments contended that, when suit is instituted challenging the denial of records or portions thereof on the basis of the exemption for trade secrets and confidential commercial or financial information, FDA may neither waive its obligation to itemize and index the disputed material nor require the intervention of the affected person. It was argued that requiring the intervention of the affected person would unfairly put smaller manufacturers at a disadvantage in that they might not be financially or physically able to itemize, index, and defend every suit involving the trade secret status of their material. It was suggested that the smaller manufacturers would have no choice but to defend only those suits involving large amounts of assertedly valuable trade secret material.

The Commissioner concludes, for the reasons stated in paragraph 73 of the preamble to the December 24, 1974 final regulation; that the requirement that the person who submitted the disputed documents index and itemize those documents and intervene to defend their trade secret status is an appropriate requirement. The Commissioner again emphasizes that, regardless of size, the affected person is in the best position to present a trade secret defense to the court.

Section 4.53 (21 CFR 4.53) revised to state more clearly that the final of the affected person to intervene to defend the exempt status of the records or, if the court requires, to itemize and index such disputed documents, will constitute a waiver of any trade secret defense, and FDA will promptly make the requested records available for public disclosure.

50. One comment contended that õ4.53 of the final regulations reflects a misconception on the part of FDA about the interests Congress was protecting in exempting trade secret and confidential commercial or financial information from disclosure. It was argued that the exemption is based on the recognition by Congress that there are both private and public interests to be served by protecting the confidentiality of trade secret and confidential commercial or financial information. It was asserted that, by proposing to waive its obligation to defend the trade secret status of disputed material, FDA does not appear to be aware of the public interest in protecting trade secret material from disclosure.

The Commissioner advises that FDA is cognizant of the congressional recognition that both public and private interests are served by protecting the confidentiality of trade secret and confidential commercial or financial information. The Commissioner, notes however, that the private interests and benefits are greater than the public interest involved, and the burden of defending the status is approximately borne by private interests who are in the best position to explain why data are valuable commercial secrets.

51. One comment suggested that the requirement in õ4.53 that the affected person itemize and index disputed trade secret material be retained but that a requirement that the affected person assist FDA in defending the trade secret status of the disputed material be substituted for the requirement of intervention by the affected person. It was also noted that, if a court declined to permit noted that, if a court declined to permit an affected person to intervene for some unknown reason, õ4.53 would allow the release of the disputed material.

The Commissioner concludes that there is no significant difference between requiring the person affected by disclosure to intervene in a suit to defend the trade secret status of the disputed information and requiring that an affected person assist FDA in defending such a suit. In either formulation of the requirement, FDA will insist upon formal intervention by the affected person and that, upon intervention, that person bear the burden of defense. The Commissioner advises, that in the extremely unlikely event that a court declines to permit intervention of an affected person. FDA will consider a request for an exception to the requirements of õ4.53 to the extent that the affected person could not, under the circumstances, formally intervene. All other obligations imposed upon the affected person by õ4.53 would remain in effect.

CLEARLY UNWARRANTED INVASIONS OF PERSONAL PRIVACY

52. Comments have asked whether the names of clinical investigators will generally be disclosed. A seeming inconsistency was noted between õ4.63(d) and õõ314.14(e)(2)(i)(a) and 314.14 (e)(4) (21 CDR 314.14(e)(2)(i)(a) and (e)(4) in that õ4.63(d) appears to provide that the names of investigator will be disclosed, absent extraordinary circumstances, while õõ314.14(e)(2)(i)(a)and 314.14(e)(4) appear to state that the names of investigators will not be disclosed Paragraphs 117 and 241 of the preamble to the December 24, 1974 regulation, it was

stated, also reflect this inconsistency.

The Commissioner advises that õ4.63 (d) states that, as a general rule and in the absence of extraordinary circumstances, the names of individuals, including clinical investigators, will not be deleted from records before disclosure. Section 314.14(e)(i) (a) applies to safety and effectiveness summaries for new drug applications (NDA's) approved prior to July 1, 1975. Those summaries consist of internal agency records that describe safety and efficacy data information. The names of investigators and any information that identifies them will be deleted because, when those internal memoranda were prepared, there was no thought that they might ever be made public and comments were often included and that would otherwise have been omitted if intended for public dissemination.

The names of, and any other information that would identify, third parties such as physicians, hospitals, investigators involved with adverse reaction reports, product experience reports, consumer complaints, and similar data and information voluntarily submitted to FDA will not be disclosed under õ314.14(e)(4). The names of investigators and any information that is contained in an NDA file after an approval letter is sent will be disclosed as part of safety and effectiveness summaries for new drugs approved after July 1, 1975, in accordance with õ4.63(d). Neither the names of investigators nor identifying information contained in an investigational new drug notice (IND) or NDA file will be disclosed before an approval letter is sent.

53. One comment noted a seeming inconsistency in that although õ4.63(a) provides for the deletion of the names and information that would identify patients in medical and similar files and makes no mention of disclosure upon showing extraordinary circumstances, paragraph 103 of the preamble to the December 24, 1974 final regulation states that disclosure of the names and information is unwarranted except in extraordinary circumstances.

The Commissioner advises that the right or privacy of individuals is paramount and that FDA will not release the names and other information that would identify patients in medical and similar files, where such release would constitute a clearly unwarranted invasion of personal privacy. Section 4.82(21 CFR 4.82) so provides. Upon further consideration, the Commissioner concludes that paragraph 103 of the preamble was in error, and should be revoked, to the extent that it stated that there would lie an "extraordinary circumstances" exception to this rule. The Commissioner anticipates no such exceptions.

54. Questions have arisen about the status of records relating to FDA investigation of clinical investigators in particular, requests have been received for records concerning the disqualification of individual investigators, lists of all investigators who have been disqualified by FDA, and records relating to investigators who have been investigated by FDA but who were not disqualified.

The Commissioner advises that upon the completion of an investigation of a clinical investigator and any regulatory action that may ensue, e.g., a hearing under Subpart F of Part 2, published in the FEDERAL REGISTER of November 2, 1976 (41 (FR 48258), records relating to the investigation, including most intragency memoranda, will be available to the public. Disclosure of records before the completion of the investigation would ordinarily interfere with the investigation: the records are therefore exempt under the seventh exemption of the FOIA (5 U.S.C. 552(b)(8) and õ4.64 (21 CFR

4.64). The public, however , has a substantial interest in FDA investigations of clinical investigators; upon completion of an investigation, disclosure of records is not a clearly unwarranted invasion of personal privacy. Records of the investigation that contain patient names and identifying details will be disclosed only after such information is deleted.

55. Questions have arisen about whether medical records or reports of adverse drug reactions are available to the subject of the records.

The Commissioner advises that medical and adverse drug reaction reports are available to the individual who is the subject of the reports. Such records would not, under õ4.111(c)(3)(vi), be available to a third person without the written consistent of the subject. However, an individual's privacy is obviously not invaded when he obtains his own medical records or adverse drug reaction report. The Commissioner notes, however, that FDA seldom obtains medical records, and has received only a few requests from persons for their own medical records. Section 4.111(c)(3)(vi) is revised to clarify this policy.

DATA AND INFORMATION PREVIOUSLY DISCLOSED TO PUBLIC

56. Comments asserted that the disclosure of trade secret information on a limited basis to physicians, veterinarians, or other health professionals for their use in caring for patients should not result in the loss of confidentiality of that information. The comments argued that such limited disclosures would not prevent the company that disclosed the information from maintaining a suit against a competitor who had unlawfully obtained the same information and should therefore not be deemed by FDA to disclosure to any member of the public. The Commissioner advises that the substance of this comment was raised and fully discussed in several paragraphs of the preamble to the December 24, 1974 regulation. The Freedom of Information Act does not contemplate selective availability of records to the public. Trade secrets must either be protected as such by the owner or they will be disclosed by the agency. This position was upheld in the opinion of Judge Smith in PMA v. Weinberger, supra.

57. Comments suggested that data and information otherwise exempt from disclosure should not lose their confidentiality by virtue of disclosure to "any" member of the public. As an alternative test, one comment suggested that the confidentiality of previously disclosed information be recognized by FDA unless the information has been disseminated to members of the public on a general basis so that the information is available to generally to competitors. Another comment suggested that the appropriate test is whether good faith efforts to prevent widespread disclosure had been taken. The Commissioner advises that use of either of the tests suggested in the comment would make decisions under the FOIA highly inconsistent and would require FDA to make an extensive ad hoc inquiry into the extent to which the information has been disseminated to the public, the extent of its availability to competitors, and the nature of the efforts taken to prevent widespread disclosure as well as a determination that those efforts were made in good faith. Such an approach is neither practicable nor contemplated by the law. The test provided for in õ4.81 (21 CFR 4.81) for determining whether the information has been disclosed to any member of the public is more practicable, can be applied consistently by the agency and is fully consistent with the congressional mandate that records disclosed unless they fall within the narrow exemptions specified.

58. One comment suggested that if previous disclosure to the public is asserted as the basis for disclosure of otherwise exempt material, the submitting person be given an opportunity to demonstrate that the disclosure, if in fact it occurred, was made with appropriate safeguards, was inadvertent or extremely limited in scope, or that in spite of the disclosure the information is not generally known outside of his business and is appreciable value. The Commissioner rejects this suggestion. If previous disclosure to the public is asserted as the basis for disclosure of otherwise exempt material, the only issue to be decided before a determination is made on the request whether the initial disclosure was lawful. If it was, the records will be released. If the initial disclosure was unlawful and the material is exempt from disclosure, the request will be denied. In short, the circumstances surrounding the initial disclosure are relevant only insofar as they relate to the determination of whether the initial disclosure was lawful.

59. Questions have arisen about whether the disclosure of trade secret material to a foreign government as a condition for obtaining marketing approval constitutes disclosure to any member of the public within the meaning of õ4.81.

The Commissioner advises that disclosure to any Federal, foreign, State or local government or government official on an official basis, does not constitute disclosure to any member of the public within the meaning of õ4.81.

60. A question has arisen about whether the disclosure of trade secret information regarding an investigational new animal drug notice or new animal drug application to inspectors of the Animal Plant Health Inspection Service. U.S. Department of Agriculture, or to a slaughter house in order to secure permission to slaughter animals for clinical research purposes, would result in the loss of confidentiality of the information disclosed. The Commissioner advises that the Animal and Plant Health Inspection Service is a governmental entity and that the disclosure of confidential information to it would not constitute disclosure to the public. Disclosure to a slaughter house in the situation described would be a necessary disclosure in the course of a routine business relationship within the meaning of õ4.81(a) and, if done with appropriate safeguards to minimize the extent of disclosure, also would not constitute disclosure to the public.

61. In the FEDERAL REGISTER of March 4, 1976 (41 FR 9317), the Commissioner amended §4.81 by adding a new paragraph (a)(3). The amendment, which was made effective immediately, codified existing FDA practice and clarified §4.81 to state explicitly that disclosures to clinical investigators and institutional review committees do not result in a loss confidentiality for the information disclosed.

DISCRETIONARY DISCLOSURE BY THE COMMISSIONER

62. A few comments asserted that there is no statutory basis for the discretionary disclosure of information by the Commissioner as provided for in õ4.82 (21 CFR 4.82). It was suggested that, if this provision is retained, provision be made for judicial review of the FDA decision to disclosure is made.

The Commissioner concludes that there is no support in the FOIA for accepting this comment. With the exceptions of trade secret material projected from disclosure by section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) and 18 U.S.C. 1905 and records the disclosure of which would constitute a clearly unwarranted invasion of personal privacy , the statutory exemptions are permissive. Agencies and departments subject to the FOIA may decide

not to disclose exempt material; they are not required to withhold it. The statute expressly commits to the discretion of the Commissioner, as the head of the agency, the decision whether exempted material should be disclosed.

63. One comment noted the apparent absence of any standards or guidelines absence of any standards or guidelines for the exercise of discretionary disclosure by the Commissioner and asserted that, without such standards or guidelines, any discretionary disclosures by the Commissioner would constitute unreasonable and arbitrary administrative action.

The Commissioner advises that the FOIA clearly embodies the concept of discretionary disclosure and contains no standards for the exercise of that discretion. This is a matter that is committed by law to the discretion of the Commissioner. It would be consistent with the FOIA for the Commissioner to decide that all material covered by one of the exemptions in that act should be disclosed under all circumstances, except when the material is prohibited from disclosure by section 301(j) and 18 U.S.C. 1905. Having decided not to adopt that alternative, it is clearly within the Commissioner's prerogative to make discretionary disclosures of material otherwise exempt from mandatory disclosure when he determines that disclosure would be in the public interest and release is not otherwise prohibited by law.

64. Questions have arisen about whether there are any circumstances in which a consultant, i.e.., a special government employee, may submit written comments to FDA with respect to a pending matter published in the FEDERAL REGISTER will be placed on display in the office of the Hearing Clerk along with all other comments. This policy was stated in paragraph 128 of the preamble to the December 24, 1974 regulations.

In one particular circumstance, however, the Commissioner has decided that the written comments of a special government employee will not be placed on public display in the office of the Hearing Clerk. Whenever a matter that has appeared in the FEDERAL REGISTER is specifically referred to a consultant for consideration as part of his official duties as a consultant, the consultant may submit his comments to the agency without the necessity that they be placed on public display in the office of the Hearing Clerk. This is true whether the consultant is a member of an advisory committee or is an ad hoc consultant. Nondisclosure of such comments is justified by the exemption for inter- and intro -agency memoranda under 5 U.S.C. 552 (b)(5).

Comments received from consultants who have been specifically and officially requested to comment will remain subject to the provisions in paragraph 128, i.e. the comments will be placed on display with all other comments.

DISCLOSURE IN ADMINISTRATIVE OR COURT PROCEEDINGS

65. Minor clarifying amendments are made in &4.63 (21 CFR 4.86).

COMMUNICATIONS WITH STATE AND LOCAL GOVERNMENT OFFICIALS

66. One comment contended that all communications between FDA and State or local government officials not under Commission or contract to FDA that pertain to the development of uniform Federal State enforcement policies should be exempt from disclosure for the duration of the deliberations on uniform policies, or longer, if so requested by a participating State, and local

official. Other comments supported the provisions in õ4.88 (21CFR 4.88) for the exchange of certain information between Federal, State, and local officials on a confidential basis.

The Commissioner concludes that õ4.88 ordinarily provides adequate protection to maintain the confidentiality of communications between Federal, State and local officials and need not now be changed. The Commissioner is confident that õ 4.88 will permit, as some comments have noted, government officials on all levels to communicate in confidence on law enforcement matters as necessary to fulfill their respective responsibilities to the public.

ADMINISTRATIVE ENFORCEMENT RECORDS

67. One comment objected to the availability for disclosure to any member of the public records relating administrative enforcement action at the time disclosure is made. Fundamental fairness, it was said, dictates that the person who is the subject of the administrative enforcement action be given an opportunity to receive the records before they are made available to the public generally. It was suggested that the records be sent by registered mail, return receipt requested, to the person is the subject of the action and that no subsequent disclosures be made until FDA receives the return receipt.
The Commissioner concludes that the recommendation is too cumbersome to administer and would significantly add to the already complex recordkeeping duties necessary for ensuring compliance by the agency with the FOIA. Moreover, it is not permissible under the FOIA to distinguish between persons in determining whether records are available for disclosure.

68. One comment objected to the availability for public disclosure of Forms FD-483 and FD 2275 (lists of observations made during food and drug plant inspections) before the availability of the establishment inspection report (EIR). The comment stated that the factual information generally contained in Forms FD-483 or FD-2275 is the same that in the EIR and that availability of such information may deprive persons of a fair trial or impartial adjudication.

The Commissioner concludes that any possible effect on a person's right to a fair trial or impartial adjudication caused by the release of Forms FD-483 or FD-2275 before the availability of the EIR is too remote and speculative to warrant a revision of the regulations. Those forms are given to the company that has been inspected and accordingly must be made available to the public contemporaneously with the initial disclosure.

FOOD AND DRUG ADMINISTRATION MANUALS

69. Paragraph 193 of the preamble to the December 24, 1974 final regulation contained a partial list of FDA manuals available to the public and a statement that "copies of these manuals may also be purchased a cost." Paragraph 193 also contained a statement that FDA does not maintain a mailing list for amendments to these manuals because of the prohibitive expense involved.

A substantial portion of the FOI requests received by FDA during fiscal years 1975 and 1976 were for FDA manuals. Additionally, because many of those manuals are frequently amended, many requests for the amendments have been received and in a few instances, mailing lists maintained.

The Commissioner is reconsidering the present agency policy of not generally maintaining mailing lists for amendments to FDA manuals and will soon explore various alternative mechanisms for maintaining mailing lists.

Additionally, the Commissioner believes that it would be useful, efficient, and in the public interest to develop a more expeditious system for making manuals available and maintaining mailings lists for them. The Commissioner has therefore initiated discussions with the National Technical Information Service (NTIS) in Springfield, Virginia, to determine whether NTIS could provide FDA manuals to the public promptly and at a reasonable cost and also maintain mailing lists for those manuals. The preliminary discussions between NTIS and FDA have been encouraging, and the Commissioner is confident that a satisfactory arrangement will be announced in the FEDERAL REGISTER. In the meantime, FDA manuals will continue to be available to the public from the FDA Public Records and Documents Center.

DATA AND INFORMATION OBTAINED BY CONTRACT

70. Questions have arisen as to whether cost and technical proposal submitted to the agency in response to a request for proposals will be disclosed.

The Commissioner concludes that all cost proposals and technical proposals that are not accepted by FDA are exempt from disclosure as confidential commercial or financial information. When a contract is awarded, however, there is generally no competitive advantage associated with any portion of the technical proposal of the successful contractor, and it will be available for public disclosure except to the extent that specific portions of the technical proposal are exempt from disclosure as trade secrets or confidential commercial information under õ 4.61. Section 4.109 (21 CFR 4.109) has been revised by the addition of a new paragraph to state this policy.

71. Paragraph 196 of the preamble to the December 24, 1974 final regulation stated that "all information obtained by the Food and Drug Administration through a contract is available for public disclosure **** ". Questions have arisen about the validity of contractual agreements entered into between FDA and outside organizations before the effective date of these regulations (January 23, 1975) that provide that no data and information obtained pursuant to the contract be disclosed to persons outside the agency.

The Commissioner advises that all such contractual agreements containing nondisclosure clauses will not be honored by FDA except to the extent that a court orders otherwise.

72. Questions have arisen about whether there are any circumstances in which information may be purchased by FDA from an outside organization under a contract that precludes further dissemination. References was made to õ 4.109 (21 CFR 4.09), which provides, without distinction, that "all data and information obtained by the Food and Drug Administration by contract *** are available for public disclosure *** unless independently exempt, and to paragraph 196 of the preamble to the December 24, 1974 final regulations, which provides that "the Commissioner concludes that the Freedom of Information Act does not permit the Food and Drug Administration to purchase information under a contract that prohibits its further public distribution, unless information is otherwise exempt from disclosure."

The Commissioner has reexamined this policy and concludes that a distinction should be made between the situation in which the agency is the sole purchaser of information and the one in which the agency is but one of a number of purchasers or subscribers, each of whom must agree not to distribute the information further as a condition for buying it. Reports obtained by contract from private organizations that are in the business of preparing and selling g the reports with clauses restricting further dissemination to protect the value of the product can properly be considered the product can properly be considered the "stock-in-trade" of such firms. The fourth exemption under the Freedom of Information Act (5 U.S.C. 522(b)(4)) may be invoked to protect the reports from disclosure to the public. Disclosure would obviously destroy the value of the reports to the outside organization and a policy requiring disclosure seriously impairs the agency's ability to obtain the information, because outside organizations have refused and will continue to refuse accept FDA as a purchaser. Both Benson v. GSA, 289 F. Supp. 590 (W.D.Wash). aff'd., 415 F.2d 878 (9th Cir., 1968) and National Parks and Conservation Assn. V. Morton, 498 F.2D 765 (D.C. Cir.1974) support this distinction.

73. Questions have arisen about whether the disclosability of results of testing and research conducted with agency funds by an outside organization pursuant to a contract is governed by õ4.105 (CFR 4.105 or .109 (21 CFR4.109).

The Commissioner advises that to the extent that a contract calls for data information covered by õ4.105 as well by 4.109 disclosability of the data and information will be determined in accordance with õ4.105(c).74. One comment requested that acceptance of a report for purposes of õ4.109 be defined as the point at which FDA begins to use the report for policy, enforcement, or other purposes.

The Commissioner advises that in some instances a report may be officially accepted before FDA begins to use it for policy, enforcement, or other purposes. Because of that possibility, no change is warranted in õ4.109.

SAFETY, EFFECTIVENESS, AND FUNCTIONALITY DATA AND INFORMATION CONTAINED IN COLOR ADDITIVE, FOOD ADDITIVE AND ANTIBIOTIC DRUG PETITIONS AND FORMS

75. Comments contended that the availability to the public of safety and functionality data contained in color and food additive petitions when the notice of filing of the petition is published in the FEDERAL REGISTER will deprive the petitioner of the competitive advantage from "lead" time that he might have over other manufacturers. It was argued that this lead time could be very significant because the final order approving a color or food additive petition is generally not issued until several years after the petition is filed.

The Commissioner concludes that the notice of filing of the color or food additive petition itself destroys any competitive advantage from lead time that the petitioner might have over other manufacturers. The Commissioner rejects the suggestion in this comment for the additional reasons state in paragraph 235 of the preamble to the December 24, 1974 final regulation.

76. Comments contended that safety and functionality data and information contained in color and food additive petitions that are not promptly filed due to deficiencies should not be made available for public disclosure after the review of the submission by FDA is complete and the petitioner informed of the deficiencies as provided in õõ8.9(a) and 121.51 (h)(1) (21 CFR 8.9(a) and 121.51(h)(1)). It was argued that the public interest is not served by disclosure at that time. The result it was asserted, is solely disclosure to competitors of the interest of the petitioner in the color or food additive at a time when the status of the substance is not formally before FDA for consideration. It was suggested that safety and functionality data and information in a deficient petition that is not filed should not be made available for public disclosure if the petitioner indicates that he intends, within a reasonable period of time to endeavor to correct the deficiencies.

The Commissioner concludes, as stated in paragraph 235 of the preamble to the December 24, 1974 regulation, that such records are properly disclosed after initial agency review. Such records provide no competitive advantage at that time and thus are not exempt from disclosure.

77. A few comments asserted that it was improper to make safety and functionality data contained in color and food additive petitions available to the public at the time the notice of the filing of a petition appears in the FEDERAL REGISTER. The preamble to the December 24, 1974 final regulation had noted that such data and information are frequently published in scientific journals and are not customarily regarded as privileged. The proper test, the comment argued, is whether the data and information in a particular petition have in fact been published in scientific journals and whether the petitioner regards and treats the data and information as privileged.

The Commissioner advises that a similar comment was fully discussed in paragraph 89 of the preamble to the December 24, 1974 final regulation. The Commissioner noted there that, if the test proposed in this comment were adopted, "decisions under the Freedom of Information Act would be highly inconsistent and would require the Food and Drug Administration to conduct an ad hoc inquiry into the way that each manufacturer handles documents submitted to the agency. Such and approach is neither practicable nor contemplated by law."

78. Comments objected to the availability to the public of safety and effectiveness data contained in an antibiotic drug file when a approval letter is sent to the sponsoring manufacturer by FDA. The comments contended that such full disclosure permits the "latecomer" to benefit from the skills and diligence of an innovator who may expended considerable research and development funds in obtaining the data and information. Disclosure the safety and effectiveness data, it was said, would discourage research by denying to the innovator the full benefits to his skills and diligence and would enable competitors to obtain marketing approval in foreign markets indirect competition with the innovator at an earlier point than would be possible were the data and information not revealed until a monograph was published.

The Commissioner does not agree with these comments. In the past, monographs have sometimes not been published in the FEDERAL REGISTER for 2 or 3 years after an approval letter was sent. The holder of the approval letter has been permitted to market the antibiotic during the "release" status, pending publication of the monograph, at which time other manufacturers would have access to the data necessary to manufacture the antibiotic. The Commissioner notes that permitting

marketing during this release period has had the effect of providing a competitive advantage through and exclusive license to the holder of the approval letter when no such license is contemplated by the statutory scheme."

The creation of this advantage, by permitting marketing during release status, is attributable solely to delays in promulgating monographs and the desire of FDA to make the antibiotics involved available to the public as soon as possible. Steps will be taken by FDA to develop procedures that will resolve this problem by assuring the publication of the monograph on a date substantially contemporaneous with the sending of the approval letter. Accordingly, the Commissioner concludes that the FOIA requires that the safety and effectiveness data and information be available upon the sending of an approval letter.

SAFETY AND EFFECTIVENSS DATA FOR NEW DRUGS OR NEW ANIMALS DRUGS

79. One comment asserted that FDA has not previously treated safety and effectiveness data for new drugs derived from studies performed on animal and human subjects under an investigational new drug notice (IND) or NDA as trade secret material and should not now, for FOIA purposes, begin to do so.

The Commissioner advises that this comment is not an accurate statement of the policies followed in the past by FDA. On the contrary, FDA has since 1938 interpreted section 301(j) of the act (21 U.S.C. 331(j)) as encompassing those data. This longstanding agency policy was fully discussed in paragraph 255 of the preamble to the December 24, 1974 final regulation.

80. Questions have arisen regarding the status of confidential data or information submitted to FDA before the filing of an IND by the potential sponsor in connection with an informal conference between representatives of the sponsor and FDA. It was suggested that such pre-IND submissions be incorporated into the IND, if later filed, and treated accordingly or, alternatively, that they be treated as voluntary submissions covered by õ4.11 and subject to presubmission review in accordance with õ4.44.

The Commissioner advises that data and information submitted to FDA before the filing of an IND by the sponsor are considered a part of the IND file if the IND is subsequently submitted, and they will be treated in the same manner as other data contained in the IND file.

81. Questions have arisen about whether data and information on investigational indications or dosage forms for an approved new drug are available for disclosure if such indications and dosage forms are being actively investigated under an IND.

The Commissioner advises that data and information about dosage forms and indications investigated under an IND or NDA will not be disclosed unless ongoing testing is already publicly known, notwithstanding the fact that an approved NDA exists for different dosage form and/or indications involving the same drug product.

82. Questions have arisen about whether data and information in an NDA file relating to an abandoned product or ingredient respecting manufacturing methods or processes, production, sales,

distribution and similar data or information, and quantitative or semiquantitative formulas are exempt from disclosure under õ314.14(g) (21 CFR 315.15(g) unless it is determined that such data and information no longer represent trade secret or confidential commercial information or financial information, or whether such data and information are available to the public upon the abandonment of the product or ingredient. It was suggested that such data and information not be made available to the public unless a determination is made that they no longer represent trade secret or confidential commercial information as defined in õ4.61 (21 CFR 4.61).

The Commissioner advises that the data and information are available if the product or ingredient is finally abandoned unless the abandoned product or ingredient. Data and information of the sort referred to by the comment are not by definition trade secret or confidential commercial or financial information if contained in an abandoned NDA file, except when the information directly affects another product or ingredient.

83. One comment supported the release, as a part of the summary of safety and effectiveness data and information, of the medical officer's reports and requested that the regulations state such reports will continue to be released after July 1, 1975. The comment also requested that the summaries now prepared by Bureau of Drugs personnel for internal review be included in the summaries of safety and effectiveness data and information made available to public.

The Commissioner advises that the medical officer's report and any summaries prepared by Bureau of Drugs personnel are available as part of the summaries of safety and effectiveness data and information only for drugs approved before July 1, 1975. For drugs approved before July 1, 1975. For drugs approved after that date summaries of safety and effectiveness data and information are specially prepared in accordance with õ314.14. Thereafter, disclosure of the medical officer's report or other internal agency records will be denied based upon the FOIA exemption for intra-agency memoranda..

84. One comment contended that withdrawal of an NDA or abandonment of a product ingredient as a result of adverse findings by an over-the counter (OTC) drug review panel should constitute per se an "extraordinary circumstance" that warrants exemption from disclosure of material concerning the NDA or ingredient.

The Commissioner advises that the regulations do not include a definition of "extraordinary circumstance," and the term embraces those rare and essentially unforeseeable situations that justify the nondisclosure of material that would otherwise be available to public. The determination of an extraordinary circumstance must, of necessity, be made on a case-by-case basis.

The Commissioner is not aware of any justification for treating data and information in an NDA file or data and information related to a product ingredient that has been withdrawn or abandoned because of adverse findings by an OTC drug review panel differently from data and information in withdrawn NDA files or data and information related to product ingredients withdrawn or abandoned for other reasons.85. Questions have arisen concerning the status of the contents of a master file which, pursuant to permission given by the basic manufacturer, is referenced by an investigator working under an independent IND, when the investigator subsequently abandons the

IND.

The Commissioner advises that the referenced master file would not be disclosable to the public upon the termination of the independent IND. The data and information in the abandoned or terminated IND file, however, would be available for public disclosure in accordance with õ314.14(f), unless that IND directly affects IND or NDA.

86. One comment asked which portions of õ314.14 of the final regulations apply to IND files and which portions apply to NDA files.

The Commissioner advises that the provisions of õ314.14 apply in their entirety to IND files subject to the following limitations: (1) If the existence of an INDA has not been publicly disclosed or acknowledged, no data or information in the file will be disclosed by FDA, (2) If an IND file's existence has been publicly disclosed or acknowledged, FDA will, upon request, confirm the existence of the IND. The Commissioner, in this circumstance, may, in his discretion, release a summary of selected portions of the safety and effectiveness and data contained in the IND file, e.g. for discussion by an advisory committee. (3) Upon the filing or approval of an NDA, although the IND is technically terminated or discontinued, the material in the IND has the same status as the material in the NDA and is subject to disclosure in accordance with the provisions of õ314.14 (4) If an IND is finally terminated or abandoned, however, as a result for example, of adverse animal findings, all safety and effectiveness data and information are available for public disclosure in accordance with õ314.14(f). (5) If the termination is temporary and sponsor of the IND is working to reactivate the file, the safety and effectiveness data retain their confidential status.

87. A number of comments asked what information regarding an IND or pending NDA will be released by FDA when the existence of the IND or pending NDA has been publicly disclosed or acknowledged, whether by disclosure to a member of the public, discussion with outsiders, marketing of the drug abroad, or appearance of published literature on the drug.

The Commissioner reemphasizes that FDA will, upon request, disclose information concerning the IND or pending NDA only to the extent that such information has been previously disclosed. In other words, once the existence of an IND or pending NDA has been disclosed or acknowledged, FDA will no longer pretend that the IND or NDA does not exist. In confirming the existence of the IND or NDA the agency will not release any data or information in the files if the data or information itself has not been previously disclosed or acknowledged, unless the Commissioner, in his discretion decides to release a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of an advisory committee or pursuant to an exchange of important regulatory information with a foreign government. Prior disclosure of otherwise exempt data and information triggers the release by FDA of only that information already released.

88. A question was raised about whether the existence of a supplemental NDA is considered confidential if the existence of the file has not been publicly disclosed or acknowledged.

The Commissioner advises that a supplemental NDA for a new use will be treated in the same manner as an IND or NDA, that is, its existence will not be disclosed by FDA unless the existence

of the application has previously been publicly disclosed or acknowledged. A supplemental NDA that is technical, e.g., one filed to reflect a reformulation to remove an ingredient such as FD&C Red No. 2 is not confidential.

89. One comment noted that the list of available computer printouts in õ4.117 (21 CFR 4.117) does not include printouts of investigational new animal drug (INAD) and new animal drug application (NADA) data and information. It was suggested that the availability of such information be specifically noted in õ4.117.

The Commissioner advises that the data and information respecting NADA's have been and will continue to be published in the FEDERAL REGISTER. Thus, there is no reason to make computer printouts available. There is no computer program currently in existence that would permit the retrieval of the INAD data and information.

90. Comments contended that studies and tests on drugs for identity, stability, purity, potency and bioavailability are an integral part of quality control procedures and are not a part of safety and effectiveness data. It was suggested that õ314.14(i) be revised to exempt such studies and tests from public disclosure.

The Commissioner concludes that although the studies and tests referred to may be considered by a pharmaceutical company conducting them as part of its quality control procedures, the results of those tests have a direct bearing on the safety and effectiveness of the drug product involved e.g., a subpotent, impure, or unstable drug may be unsafe or less effective than anticipated relative to an identical drug product that is potent, pure and stable. Such tests are accordingly properly classified, for purposes of these public information regulations, as safety and effectiveness data and information. Summaries are therefore available to the public.

91. A large number of comments duplicated previous objections to the disclosure of safety and effectiveness data and information contained in IND or NDA files. These comments were fully discussed and disposed of in the preamble to the December 24, 1974 final regulations. These include comments about the situation in which the termination of one IND or NDA and disclosure of data and information relating to it may affect another IND or NDA that has not been terminated-discussed in paragraph 260 of that preamble; the adverse effect of the release of safety and effectiveness data on competition in foreign markets-discussed in paragraphs 245 and 269 of that preamble; the Commissioner's conclusion that safety and effectiveness data in abandoned, unapprovable, or withdrawn NDA's, or those for which a determination has been made that the drug product is not a new drug or that the drug maybe marketed without submission of safety and/or effectiveness data and information, will be available for public disclosure-discussed in paragraphs 267 through 272 of that preamble; the determination that the existence of an IND notice will not be regarded as confidential if the drug is marketed aboard if published literature exists on the drug-discussed in paragraph 240 of that preamble; and the contention that the manufacturer should have the final say on the contents of all summaries of safety and effectiveness data-discussed in paragraph 260 of that preamble.

92. In the FEDERAL REGISTER of March 4, 1976 (4 FR 9317), the Commissioner amended õ314.14(f) to correct an inadvertent omission. Before the amendment, paragraph 269 of the

preamble to the December 24, 1974 final regulation contemplated, but õ314.14(f) did not expressly provide for, nondisclosure of safety and effectiveness data and information in abandoned, terminated, or withdrawn IND's or NDA's. if extraordinary circumstances were shown. The "extraordinary circumstances" language was also inadvertently omitted from õ514.11(f) (21 CFR 514.11(f), the new animal drug counterpart to õ314.14(f), and was not added by the March 4, 1976 amendment. Accordingly, õ514.11(f) is amended to correct the inadvertent omission.

A PROTOCOL FOR A TEST OR STUDY

93. Several comments asserted that protocols for tests or studies reflect years of experience in a particular field, offer a competitive advantage, are customarily held in confidence by members of the industry, and should therefore be treated as trade secrets.

The Commissioner concludes that, as a general rule, protocols for tests or studies are not properly regarded as trade secrets. However, protocols for tests or studies may be regarded as trade secrets if the fact in a specific case warrant such a conclusion. Without attempting to list all the relevant factors, the Commissioner notes that those factors include the cost involved in developing the protocol, the extent to which the protocol is unique, as well as other criteria contained in the "Restatement Comment" definition of trade secret and discussed in paragraph 81 of the preamble to the December 24, 1974 final regulation.

ADVERSE REACTION REPORTS

94. One comment agreed that reports of adverse reactions in an IND file should be provided on request to individuals participating in a study involving an IND, as provided in õ312.5(c) (21 CFR 312.5(c). It was contended, however, that adverse reaction reports on INDs should also be available to clinical investigators, physicians, and other health professionals. It was argued that these individuals need such reports to evaluate properly research projects involving particular drug products and in caring for patients. It was also asserted that release of adverse reaction reports on IND's would encourage manufacturers to be honest in informing investigators when investigations are terminated because of adverse results instead of the alleged current practice of attributing such termination to "commercial" reasons.

The Commissioner note that pursuant to õ312.1(a)(6) (21CFR 312.1(a)(6)), the regulations governing investigational new drugs, the sponsor of the drug is required to report promptly to all "investigators" any findings associated with use of the drug that may suggest significant hazards, contraindications side-effects and precautions pertinent to the safety of the drug." Accordingly, the Commissioner concludes that it is not necessary and would be superfluous to make such reports available to investigators under the FOIA. Any information that the agency receives is required also to be in the possession of all investigators

PRODUCT INGREDIENTS

95. Questions have arisen about the status under these regulations of certain product formulation information for packaging materials for use with various products, including drugs. Two specific questions have been raised; (1) Will quantitative or semiquantitative formulas for drug-packaging

materials submitted to FDA as part of a master file for use with one or more NDA's be available to the public; and (2) will qualitative formulas, i.e., the names of the chemical components of drug-packaging materials, submitted to FDA as part of a master files for use with one or more NDA's be available to the public.

The Commissioner concludes that quantitative and semiquantitative formulas for drug-packaging materials quality as trade secrets under õ4.61 and thus are exempt from disclosure. Likewise, qualitative formulas for drug-packaging materials are exempt from disclosure under õ4.61.

ASSAY METHOD OR OTHER ANALYTICAL METHOD

96. One comment stated that the regulations are not clear about when an assay or analytical method serves no regulatory or compliance purpose. It was suggested that õ314.14(e)(6) be revised to provide that assay or analytical methods would be available after an approval letter is sent unless the method constitutes a trade secret as defined in õ4.61.

The Commissioner advises that assay or analytical methods, by their nature, are ordinarily devised and disseminated specifically for regulatory or compliance purpose. As was stated in paragraph 288 of the preamble to the December 24, 1974 final regulation, assay and analytical methods are available to and used by a large number of persons, including regulatory officials on the Federal, State, and local level to ensure compliance with the law. They do not provide a competitive advantage for one manufacturer over another. Accordingly, they will disclosed as a matter of course, with the narrow and rare exception that an assay or analytical method that is not used for any regulatory function whatsoever, that is, one that is not used by anyone to ensure compliance with the law, will be exempt from disclosure unless the method has previously been made available to any member of the public within the meaning of õ4.81.

MANUFACTURING METHOD OR PROCESS INCLUDING QUALITY CONTROL PROCEDURES

97. Clarification has been requested of the Commissioner's statement in paragraph 290 of the preamble to the December 24, 1974, final regulation that "a company's manufacturing methods and processes, quality control procedures, and quantitative formulas are per se exempt from disclosure unless previously disclosed or later abandoned ****

The Commissioner advises that the phrase "per se exempt" was used to indicate that manufacturers need not, as had been proposed, routinely submit a statement to FDA concerning prior disclosure or abandonment of manufacturing methods and processes, quality control procedures, and quantitative formulas. However, information is not automatically exempt from disclosure merely because it is denominated by the manufacturer as, for example, a quality control procedure. Furthermore, manufacturing methods and processes and quality control procedures in particular are available to the public where, for example, the method, process or procedure is described in the literature. It is not usual to find a detailed description of a manufacturing method in standard reference book. In such a situation, a claim of confidentiality for the information unsupported.

BIOLOGICAL DRUGS

98. A few comments contended that safety and effectiveness data and information for biologics should be accorded the same status as similar data and information for new drugs under õ314.14.

The Commissioner concludes that this comment has been fully discussed and disposed of in paragraph 302 of the preamble to the December 24, 1974 final regulation. The comments presented no new information and raised no new issues warranting further discussion.

RADIATION CONTROL FOR SAFETY AND HEALTH ACT OF 1968

99. The Food and Drug Administration, through its Bureau of Radiological Health, enforces the Radiation Control for Safety and Health Act of 1968.. Under that act and implementing regulations, manufacturers are required to submit several different types of reported to FDA, e.g., initial and annual reports under õõ1002.10 and 1002.,11 (21 CFR 1002.10 and 1002.11).

The Commissioner advises that the reports and records maintained by the Bureau of Radiological Health are under review to determine their status generally under the FOIA. Upon completion of that review, a notice of proposed rule making will be published in the FEDERAL REGISTER setting forth proposed amendments to these regulations to state, as has already been done for most other agency records, the status of the records under the FOIA.

MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS

100. The Medical Device Amendments of 1976 (Pub. L. 94-295) amending the Federal Food, Drug , and Cosmetic Act provide substantial new authority to FDA to regulate medical devices and diagnostic products.

The Food and Drug Administration will be receiving many new types of reports and information about those products as a result of the amendments. These reports and records will be reviewed to determine their status under the FOIA. Upon completion of that review, a notice proposed rule of that review, a notice of proposed rule making will be published in the FEDERAL REGISTER setting forth proposed amendments to these regulations to state the status of the records under the FOIA.

This final order was proposed prior to executive Order 11821, requiring agencies in the executive branch to review regulatory and legislative proposals they initiate for inflation impact, and so does not require inflation impact review.

SECTION III

Answers to Frequently Asked Questions

Section III

Answers to Frequently Asked Questions

Introduction

The following recurring questions and their answers may assist employees when sharing information with persons outside of the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA), and, in certain cases, when sharing information outside of FOIA. This document is intended to supplement the procedures on FOIA, Sharing Non-Public Information with Federal Government Agencies, with State and Local Government Agencies and with Foreign Government Agencies.

In section III

This section contains the following topics

A. 5 U.S.C. § 552(b)(4), Confidential Commercial and Trade Secret Information (21 C.F.R. § 20.61)

Confidential Commercial Information

1. What is confidential commercial information?

5 U.S.C. § 552(b)(4) of the FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." Confidential commercial information is valuable data or information which is used in one's business and, if voluntarily submitted by the information's owner to FDA, is of a type customarily not disclosed to the public by the person to whom the information belongs or, if not voluntarily submitted, is information which, if disclosed by FDA would be likely to cause substantial harm to the competitive position of the person to whom the information belongs or impair the agency's ability to obtain similar data in the future. The Trade Secrets Act (18 U.S.C.
§ 1905) prohibits the disclosure of confidential commercial information unless specifically authorized by law. Violations of this statute can carry criminal penalties.

2. What are examples of "confidential commercial" information?

Examples of confidential commercial information might include certain information about a manufacturer's operations, style of work, apparatus, identity, confidential statistical data, amount or source of income (e.g., a company's list of customers), list of suppliers, production data, sales data, distribution data, profits or losses, overhead or operating expenditures (of any person, firm, partnership, corporation or association), financial information, protocols, safety and effectiveness data, research data, technical designs, etc. [See 21 C.F.R. § 20.61(b), and comment 78 in 39 *Federal Register* 44602 (December 24, 1974), hereafter referred to as "1974 Regulations."] Confidential commercial information is often found is the same kinds of documents that contain trade secrets. For example, an Establishment Inspection Report (EIR), or a medical officer's review, may contain confidential commercial information, and occasionally may contain trade secret information. Confidential commercial information is not to be confused with trade secret information, explained at **Q5**, although both are protected by FOIA Exemption 4 [5 U.S.C. § 552(b)(4)]

3. May the name of a federal government agency that is a customer of a particular firm be released to the public under FOIA pursuant to a request for the firm's distribution list? May the names of non-government customers on the list be disclosed?

The name of a government account is not considered confidential commercial information because the public has a right to know how the government is spending its money. Thus, the names of federal government agency accounts may generally be released. However, unless the firm has already disclosed the identity of its non-government customers, the remainder of the list may need to be redacted as confidential commercial information

4. Should FDA disclose the name of the U.S. Importer found on FDA Form 701?

Generally, FDA redacts, as confidential commercial information, the name of the U.S. Importer found on FDA Form 701.

Trade Secret Information

5. What are examples of trade secret information?

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing (including quality control procedures) of trade commodities and that can be said to be the end product of either innovation or substantial effort. Examples of trade secrets include materials used in manufacture which are not immediately identifiable, manufacturing processes, quality control procedures, sterilization techniques, formulas, schematics or circuit diagrams, and related data not in the product labeling. Trade secrets are frequently found in EIR's, device Pre-market Notifications [510(k)'s], device Pre-market Approval Applications (PMA's), Investigational Device Exemptions (IDE's), New Drug Applications (NDA's), Investigational New Drug Applications (IND's), New Animal Drug Applications (NADA's), Investigational New Animal Drug Applications (INAD's), pending biological product files including Product License Applications (PLA's), and certain technical proposals or bids from contractors, etc. There must be a direct relationship between the trade secret and the production process [see 21 C.F.R.§ 20.61(a)]. Trade secrets are protected from disclosure under FOIA Exemption 4. In addition, the Trade Secrets Act (18 U.S.C. § 1905) and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 331(j)] restrict the agency§s ability to disclose trade secret information. Failure to comply with 18 U.S.C. § 1905 or 21 U.S.C. § 331(j) may result in the imposition of criminal penalties.

B. 5 U.S.C. § 552(b)(5), Deliberative Process; Attorney-Client and Attorney Work Product Privileges (21 C.F.R. § 20.62)

6. What is Attorney General Janet Reno's "foreseeable harm" test, and how does it affect the disclosure of documents under 5 U.S.C. § 552(b)(5) of the FOIA, which covers inter-agency or intra-agency records that are deliberative in nature and prepared prior to a final agency decision, and the attorney-client and attorney work product privileges?

Attorney General Janet Reno set out what is commonly referred to as the "foreseeable harm" test in her October 4, 1993, memorandum "for Heads of Departments and Agencies." In that memorandum, she stated "The Department will no longer defend an agency's withholding of information merely because there is a 'substantial legal basis' for doing so. Rather, in determining whether or not to defend a nondisclosure decision, we will apply a presumption of disclosure...[I]t shall be the policy of the Department of Justice to defend the assertion of a FOIA Exemption only in those cases where the agency reasonably foresees that disclosure would be harmful to an interest protected by that Exemption. Where an item of information might technically or arguably fall within an Exemption, it ought not to be withheld from a FOIA requester unless it need be."

The "foreseeable harm" test should be used in those situations where a FOIA Exemption applies, but FDA has discretion to disclose the information anyway. This is generally the case when FDA's interest will be the only interest affected by disclosure [e.g., Exemptions § 552(b)(2) (internals rules and practices); § 552(b)(5) (deliberative process materials), and § 552(b)(7)(A) (records or information compiled for law enforcement purposes disclosure of which could interfere with law enforcement proceedings)]. Therefore, even if the information may be withheld under Exemption § 552(b)(5) [or under § 552(b)(2) or § 552(b)(7)(A)], FDA should disclose it unless disclosure could cause "foreseeable harm" to FDA's interests as otherwise protected by those exemptions. However, the "foreseeable harm" test should <u>not</u> be used where the basis for withholding information is Exemption § 552(b)(4) (confidential commercial or trade secret information) or Exemption § 552(b)(6) (personal privacy information), as these exemptions directly affect the interests of third parties.

7. May FDA disclose Advisory Committee meeting minutes under FOIA?

The final minutes of an open Advisory Committee meeting are releasable. However, if the Advisory Committee meeting is closed, the minutes generally are not releasable.

8. May FDA protect documentation about an attorney's advice to a client (e.g., a Center representative) under Exemption § 552(b)(5)?

Yes. The attorney-client privilege is well established and can typically be invoked to withhold facts provided by a client (e.g. a Center representative) to the attorney, legal opinions or advice provided by the attorney to the client, and communications between attorneys which reflect information provided by the client.

9. Are draft documents protected under Exemption § 552(b)(5) even after a final report has issued?

Yes. Draft documents, such as drafts of policy making documents or regulations, prepared by FDA generally are considered to be predecisional deliberative documents that may be withheld under FOIA Exemption § 552(b)(5). The fact that the draft has been superseded by a final document does not cause the draft document to lose its protection under this exemption. However, like other Exemption § 552(b)(5) records, which are subject to discretionary disclosure, FDA should not withhold the draft unless disclosure meets the "foreseeable harm" test. The "foreseeable harm" test would be met, for example, if disclosure would chill frank and candid discussions among FDA employees about issues addressed in the draft document. (See also comment 183, 1974 Regulations.)

10. May the opinion of the investigator be redacted from a Form FDA-483 or an EIR?

The investigator's opinion should not be included in the Form FDA-483 [see "Investigations Operations Manual," (IOM) (January 1998), section 512.2, "Non-Reportable Observations."] A decision to redact an opinion from a Form FDA- 483 that had already been issued to the inspected firm, should be done in consultation with the Office of Chief Counsel. Facts to consider, on a case-by-case basis, are that: (1) the Form FDA-483 is a form that is prepared to be distributed to the firm [i.e., it is an administrative enforcement record under 21 C.F.R. § 20.101(a)], and (2) because redaction of the investigator's opinion after issuance of the form to the firm would serve to protect FDA's interests, rather than a third party's, depending on the circumstances, subsequent withholding of this information might not be defensible if challenged in Court.

In an EIR, on the other hand, the investigator's opinion may be redacted if it is part of the deliberative process of the inspection and has not already been released to the firm or another member of the public. An example of when it might be appropriate to redact would be where disclosure would chill the frankness and openness of FDA's deliberative processes. However, opinions, recommendations, and other deliberative information otherwise protected under FOIA Exemption
§ 552(b)(5) (see 21 C.F.R. § 20.62) should nevertheless be disclosed if they do

not meet Attorney General Janet Reno's "foreseeable harm" test.

11. What are examples of documents that might contain information that is non-public under FOIA Exemption § 552(b)(5)?

Examples of documents that might contain information that is non-public under this exemption include minutes of meetings, written recommendations to take some regulatory or enforcement action, drafts of policy-making documents such as draft regulations, even though the final version of the document will be made public, and requests for a legal opinion as well as the opinion itself, etc.

C. 5 U.S.C. § 552(b)(6) and (b)(7)(C), Personal Privacy (21 C.F.R. §§ 20.63 and 20.110)

12. What information in FDA's records about a current government employee may be released?

As to current government employees, the name, title, grade, position description, salary, work address, and work telephone number for every FDA employee is available for public disclosure [21 C.F.R. § 20.110(a); comment 43, 1974 Regulations]. Statistics on prior employment experience of present FDA employees, and subsequent employment of past employees, are available for disclosure [21 C.F.R. § 20.110(b); comment 98, 1974 Regulations]. Release of this information is premised on the notion that civilian federal employees have no expectation of privacy regarding their names, past and present titles, grades, salaries and duty.

Also, the Department of Justice (DOJ) issued a September 1982 "FOIA Update," that states that it is the policy of the DOJ to release additional information such as: post-graduate or technical education in preparation for the employee's profession; (1996 DOJ FOIA course handout indicated that the name and location of the college may be released), all prior employment in state or federal government positions; prior employment in the private sector related to an employee's duties; awards and honors received; membership in professional groups, the fact that an employee was recommended for promotion, appointment or reassignment; letters of commendation from professional associates and colleagues; appointment affidavits and oaths of office; and creditable service for leave purposes.

13. What information about current government employees (or other individuals) may be withheld from a FOIA requester?

FOIA Exemption 6 [5 U.S.C. § 552(b)(6)] protects information about individuals, including FDA employees, found in personnel, medical and similar files when the disclosure would constitute a clearly unwarranted invasion of personal privacy. This protection has traditionally been extended broadly and generally has been the basis for withholding information pertaining to an

employee's personal life and family status, such as place and date of birth; age; marital status; home address and telephone number; medical records; details of health and insurance benefits; the substance of promotion recommendations; supervisory assessments of professional conduct and ability; information concerning or provided by relatives and references; prior employment not related to the employee's present occupation; primary education; allegations of misconduct or arrests; and military service number and social security number.

FDA will deny as a clearly unwarranted invasion of personal privacy a request for the release of "all" records relating to a particular employee, unless the request is accompanied by the written consent of the named employee. However, FDA will release a specific record, if requested, as appropriate [comment 108, 1974 Regulations; 21 C.F.R. § 20.63(e)].

14. How is the criteria "need to know" satisfied when considering whether information about an employee should be released to other personnel within the agency?

If you receive a request for information about an employee from another FDA employee, you should first consider whether the information requested is a record subject to the Privacy Act. The Privacy Act protects individuals against unwarranted invasions of their privacy stemming from federal agencies' collection, maintenance, use, and disclosure of information about them. However, the Privacy Act applies only to information that is about an individual and that is included within a system of records. A system of records includes those records that are under FDA's control, and which contain information that the Agency retrieves by the individual's name or some other personal identifier. Not all information about a person in the Agency's files is covered by the Privacy Act. *It is only where such records are retrieved by the individual's name or a personal identifier that the Privacy Act may apply.* A list of Privacy Act systems notices describing the types of FDA records covered by the Privacy Act has been published in the Federal Register [*Federal Register* Vol. 59, No. 248, p. 67087 (Wednesday, December 28, 1994)]. If you have a request for a record about a person and are unsure whether the Privacy Act applies, you should contact FDA's Privacy Act Officer in HFI-35 (301-827-6500) or one of the attorneys specializing in disclosure matters in the Office of Chief Counsel (OCC) (301-827-1137).

Generally, records protected by the Privacy Act cannot be disclosed to any third party, including FDA employees, without the consent of the individual to whom the record relates. However, there are a number of exceptions to the general rule that Privacy Act records may not be disclosed without the consent of the individual. One such exception is that Privacy Act records may be disclosed to other FDA personnel on a "need to know" basis.

The "need to know" exception authorizes the intra-agency disclosure of a record

for necessary, official purposes. One factor to consider in determining whether the "need to know" standard has been met is whether the stated purpose for receiving the requested information is established by the position description of the employee who wants to know the privacy information. Examples include a requesting employee with responsibility for making employment and/or disciplinary decisions about the individual who is the subject of the record, such as the employee's direct-line supervisor, and the record relates to the employment decision. (It may not be appropriate to release the information to a requester solely based on the requester's position or title. Consider that in conjunction with the purpose for which the document is requested.) The requester should submit the request in writing to the office that originated the protected information stating with specificity the need for the information, the business relationship of the requester to the employee, i.e., direct line supervisor, upper management, etc., the requester's authority to request that information, and the steps the requester will take to protect the confidentiality of the privacy information.

15. What steps should be taken to verify that the identity of the individual requesting personal privacy information protected by either the Privacy Act or FOIA, 5 U.S.C. § 552(b)(6) or (b)(7)(C) is the subject of the records, or is the parent or legal guardian of the subject of the records?

The amount of documentation necessary to verify the identity of the requester may vary as set out below.

1. If an individual requests records about himself or herself, obtain a letter from the requester/subject that sets out the requester's full name, current address, and date and place of birth. The requester must sign the request and the signature must be either notarized or submitted to FDA under 28 U.S.C. § 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. No specific form is required; however, you may wish to use the attached model form ("ATTACHMENT: CERTIFICATION OF IDENTITY"). To help FDA locate the appropriate files, it would be helpful to have the requester/subject include his or her social security number as well.

2. If the requester is making a request as the parent or legal guardian of a minor or as the legal guardian of someone determined by a court to be incompetent, for access to records about that individual, obtain a letter from the requester that sets out:

   A. the identity of the individual who is the subject of the record, by providing the name, current address, date and place of birth, and, if possible, the social security number of the subject,
   B. the information about the requester according to the information in paragraph 1 of this answer,
   C. a statement that the requester is the parent or legal guardian of

that individual, which the requester may provide by providing a copy of the individual's birth certificate showing the requester's parentage or by providing a court order establishing the guardianship,

D. a statement that the requester is acting on behalf of that individual/subject in making the request, and

E. signature and either notarization or a statement in accordance with 21 U.S.C. § 1746, as described above in paragraph 1.

3. Generally, the requester also should be the recipient. If the requester/subject is not also the recipient, e.g., the subject of the record wants the information sent to a third party attorney, etc., records containing a "first-party" redaction may be released to a third party only upon verification of the identities of both the requester and the recipient. This can be accomplished by obtaining evidence such as that set out in paragraphs 1 and 2 of this answer.

16. How should FDA respond if the requester of a record that is protected by personal privacy exemptions under FOIA [5 U.S.C. §§ 552(b)(6) or (b)(7)(C)] does not comply with FDA's request for evidence verifying that s/he is either the subject of the requested record or, in the case of a minor child, the parent or legal guardian of the subject of the record?

If the requester refuses to provide verification documentation, then, for Privacy Act requests, refuse to respond to the request, stating the reason why. For requests under FOIA for law enforcement records concerning the subject individual, use a "Glomar" response. That is, indicate that FDA can neither confirm nor deny the existence of the requested records. (The term, "Glomar" was first recognized in the national security context about whether the Central Intelligence Agency could refuse to confirm or deny its ties to Howard Hughes' submarine retrieval ship, the *Glomar Explorer*.) Using a "Glomar" response in the context of privacy is appropriate because "disclosure of the mere fact that an individual is mentioned in an agency's law enforcement files carries a stigmatizing connotation." [U.S. Department of Justice (DOJ), "FOIA UPDATE," "Privacy 'Glomarization'" Winter 1986]. (The fact that FDA has requested evidence of identity is a procedure to start the process of responding to a request. It does not imply that a search for the record has begun, nor that a record exists.)

DOJ has advised the Office of Enforcement (OE) that it uses the Glomar response whenever the FOIA requester refuses to provide the DOJ-requested verification, whether or not the request is for a law enforcement record. However, if the record requested is not an FDA law enforcement record, contact OCC for guidance.

If the subject of record is deceased, then the information generally is releasable

unless, due to the graphic details of the information such as the circumstances related to the individual's death, release of the record constitutes a clearly unwarranted invasion of the privacy of the interests of the deceased's family.

17. What type of information about an individual is protected from disclosure under FOIA Exemptions §§ 552 (b)(6) and (b)(7)(C) [see 21 C.F.R. §§ 20.63, 20.64 (a)(3), 20.110, and 20.111(c)(3)]?

FOIA Exemption § 552 (b)(6) protects from disclosure information about an individual that is contained in personnel or similar files, the disclosure of which "would constitute a clearly unwarranted invasion of personal privacy." Exemption § 552 (b)(7)(C) covers information compiled for law enforcement purposes, the disclosure of which "could reasonably be expected to constitute an unwarranted invasion of personal privacy." In the context of records in FDA's files concerning a patient or another individual, such as adverse reaction reports, product experience reports, and consumer complaints [21 C.F.R. § 20.111(c)(3)], privacy information appropriate for redaction might include such "personal identifiers" as the individual's name, initials, social security number, dates of birth and/or death, financial account numbers and name of bank on receipts or checks, identification numbers (such as those assigned by health care providers), home address, home phone and facsimile numbers, health care provider (such as a referring or treating physician or managed care company) name/address/telephone/facsimile number, and if appropriate, insurance company name and account number, witness's name and address. On those records identifying one or more relatives of the patient, personal privacy information relating to these individuals also should be redacted before disclosure.

Unless it would identify the patient, FDA may not need to redact the gender, age, relationship (son, wife, etc.), or diagnosis. Also, there is no need to redact personal privacy information in a document to the extent such information is already in the public domain. This would apply, for example, where a document containing privacy information was issued by or filed with the court (look for the court's receipt date stamp) unless the court sealed the document. This reasoning would similarly apply where privacy information has been published or lawfully disclosed in some other public forum. Again, the extent of redaction is contingent upon the subject matter and degree to which the information could identify the person entitled to the privacy. However, FDA traditionally has taken a conservative approach when considering the extent to which personal privacy information should be redacted. For example, FDA generally redacts personal privacy information on records requested by any member of Congress.

18. What information about a blood donor or recipient should be redacted from FDA records?

Information about a blood donor or recipient might be found in records such as those provided to FDA by a blood bank or similar establishment, or by a health care provider. Redact personal privacy information including, but not limited to, the name of the blood donor or blood recipient name, and the donor identification number. (Note: FDA has redacted this information in records even to Congress.)

19. What documentation must FDA have before it discloses non-public personal privacy information to a person who requests a copy of an adverse reaction report, product experience report, consumer complaint or similar record relating to a specific individual or specific incident?

The request for a copy of that type of record relating to a specific individual or a specific incident will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to FDA and the individual who is the subject of the report [21 C.F.R. § 20.111 (c)(3)(vi)]. If the requester is the individual who is the subject of the report, the record will be disclosed upon request and verification of identity (see **Q15** and **Q16**). If the requester claims to be the parent or legal guardian of the individual who is the subject of the record, obtain the appropriate verification of identity before releasing the record (see **Q15**and **Q16**).

20. To what extent, if any, should the names of the firm and the employees of the inspected firm be redacted in an EIR?

Unlike individuals, corporations have no privacy protection under FOIA. Therefore, the name of the firm can be released. With respect to the names of the firm's employees, FDA traditionally has released the names of key industry employees, but not lower level employees, identified in the EIR. The theory for releasing the names of firm's key employees and officers in the EIR is that these individuals are in a position of authority and have less of an expectation of privacy than lower level employees who basically only follow orders. Also, the lower-level employees are less responsible for a firm's policy and procedural decisions. Therefore, the public's interest in knowing the identities of the firm's high-level and key individuals generally is stronger than knowing the identities of the lower-level employees.

D. 5 U.S.C. § 552(b)(7) Law Enforcement Records

1. When is the Record Closed, and Questions Related to Establishment Inspection Reports (EIR's) [21 C.F.R. §§ 20.64 and 20.101(c)].

21. When is a record "closed?"

Generally, Exemption § 552(b)(7)(A) may be invoked to protect the information in a law enforcement record if the law enforcement proceeding is pending and disclosure of the information could reasonably be expected to interfere with that proceeding. An EIR is a law enforcement record that FDA generally will withhold under FOIA Exemption 7(A) until the record is closed. However, the Commissioner may exercise his discretion under 21 C.F.R. § 20.82 to release the EIR before the record is closed [see 21 C.F.R. § 20.101(b) and (c)]. An EIR is considered closed when FDA has concluded its review of the firm's activities and decides that no additional administrative or regulatory action is warranted or dictated. This generally does not occur until after FDA has issued a Warning Letter to the firm and the firm has responded.

Mere issuance of the Warning Letter does not close the EIR record, because a Warning Letter is informal and advisory and is not a final FDA action. If the firm's response is adequate, FDA may conclude that no further administrative or regulatory action is dictated. Otherwise, FDA may decide to reinspect the firm or, in the absence of a firm's response or FDA's follow-up inspection, FDA might conclude the record to be closed after consideration of the factors listed below.

1. The circumstances that lead to the initial inspection. Have the circumstances changes. Was there a serious risk to public health?
2. The findings upon initial inspection. What was the nature of the deficiencies? Were they numerous, grave, or did they represent a widespread problem in the firm? Why did FDA classify the inspection OAI?
3. The profile of the firm. What is the firm's history of compliance? Its pattern for truthfulness?
4. The steps the firm has taken to correct the deficiencies.
5. The evidence the firm has provided that it corrected the deficiencies (such as photographs or receipts).
6. Conversations with the firm's officials. Was the conversation with a high-ranking official?

After thoughtful consideration, if FDA determines that no further review and no administrative or regulatory action is dictated, and that this determination is in the interest of public health and defensible, it has established the rationale for

concluding that the record is closed. The decision should be documented and include when it was made, who was involved in the decision, and the basis for the decision. The documentation will serve two purposes: (1) it will develop precedent to be followed in the future to ensure consistent decisions, and (2) it will establish the administrative record if the decision is challenged or a history of events is needed.

22. Is the record of an EIR inspection that was classified as OAI considered "open" for FOIA purposes until the firm is reinspected and the subsequent EIR is classified NAI or VAI?

Assuming the classification of the first EIR as OAI was correct, the record is closed when FDA concludes that no further administrative or regulatory action is dictated (see answer to prior question). The classification of the first EIR as OAI does not change. However, if there is a follow-up inspection, the classification of the second EIR could be NAI or VAI if appropriate. Generally, the classification of NAI or VAI indicates that FDA considers that no further administrative or regulatory action is warranted.

23. May FDA release all the EIR's for an inspected firm?

Once FDA determines that no further administrative or regulatory action is warranted or dictated (i.e., the record is closed), FDA may properly redact and release all earlier related EIR's for the inspected firm even if classified as "OAI."

24. What may be released when the EIR record is closed and the EIR is requested?

The EIR generally is available for public disclosure after consideration of administrative and regulatory enforcement action has concluded, i.e., once the record is closed. Under FMD 145, FDA will affirmatively disclose the EIR, with the appropriate first-party redaction, to the inspected firm when the record is closed without the firm having to submit a FOIA request.

In response to a FOIA request, FDA will disclose the EIR itself properly redacted of confidential commercial, trade secret, or personal privacy information. On occasion, it may also be appropriate to redact certain deliberative information such as the opinions or recommendations of the investigator. If the FOIA requester makes a specific request for them, the following documents also may be disclosed with redactions of exempt information as appropriate: the cover sheet, the background material supporting the EIR, the corrective action plan, and the EIR's attachments (including collection reports), exhibits, or investigator notes. (The name of the manufacturer may remain in the collection report if it is on the product's label.) However, these records relating to the EIR will only be disclosed if the EIR itself has already been released.

25. Where do we send, for processing, FOIA requests for EIR's on inspected

foreign firms?

Requests for foreign EIR's are sent to the component that has the official records; that is, for human drugs, the Center for Drug Evaluation and Research, for those inspections conducted by or for the Center for Biologics Evaluation and Research, to that Center, and for medical device inspections completed in FY 97 or later, to the Center for Devices and Radiological Health. The official records of EIR's for foreign inspections related to the other Centers are maintained by the Office of Regulatory Affairs' (ORA) Division of Emergency and Investigational Operations. The offices that have the official records also are responsible for redacting the documents in accordance with any applicable FOIA exemptions.

26. What FDA component has the responsibility for final classification of an EIR for a clinical investigator?

The Center has the responsibility for final classification of an EIR for a clinical investigator.

27. What are the general rules for FDA's disclosure of administrative enforcement records such as EIR's, either pursuant to a FOIA request or on its own initiative?

The regulations at 21 C.F.R. § 20.101 address administrative enforcement records, including Warning Letters and untitled letters, Forms FDA-483 [21 C.F.R. § 20.101(a)], EIR's [21 C.F.R. § 20.101 (b) and (c)], and other records set out in the regulations. Records relating to administrative enforcement action that have not been disclosed to the public, such as EIR's [21 C.F.R. § 20.101(c)], constitute investigatory or law enforcement records. Such records are exempt from disclosure to the public under 21 C.F.R. § 20.64 and may be withheld, unless the Commissioner exercises his discretion to release them under 21 C.F.R. § 20.82.

EIR's and other law enforcement records covered under 21 C.F.R. § 20.101(c) are normally available for release to the public after the record is closed, unless the agency decides to make a discretionary disclosure of the record before it is closed (see 21 C.F.R. § 20.82). However, before disclosure to the public through the FOIA process, or by FDA on its own initiative, these records should be redacted for confidential commercial, trade secret, and personal privacy information as appropriate.

Unlike EIR's and other records covered under 21 C.F.R. § 20.101 (b) and (c) that are not prepared for disclosure to the public, administrative enforcement records covered under 21 C.F.R. § 20.101(a) are records that are normally prepared for disclosure outside the agency. These records, such as Warning Letters and Forms FDA-483, are available for public disclosure once disclosed to any member of the public, including the subject firm. See **Q28 and Q30.**

Consider the information in "Table 1" below before disclosing a record covered by 21 C.F.R. § 20.101(c), such as an EIR.

TABLE 1. 21 C.F.R.§§ 20.101(b) and (c): Administrative Record, Such as an EIR, that is not Routinely Prepared for Disclosure to the Public [21 C.F.R. § 20.101(c)], and an Investigatory Record (21 C.F.R. § 20.64).

	On FDA's Own Initiative	FOIA Request
Redacted	Record may be disclosed to public after redaction of confidential commercial, trade secret and personal privacy information once the record is closed, or, if the record is not closed, where the agency has decided to make a discretionary disclosure (21 C.F.R. § 20.82) even though record is otherwise exempt under FOIA Exemption 7.	Record may be disclosed to public after redaction of confidential commercial, trade secret and personal privacy information once record is closed, or, if the record is not closed, where the agency has decided to make a discretionary disclosure (21 C.F.R. § 20.82) even though record is otherwise exempt under FOIA Exemption 7.
Unredacted	The record may be disclosed to public after record is closed, or if the record is not closed, where the agency decides to make a discretionary disclosure. Confidential commercial, trade secret, or personal privacy information should be redacted unless the submitter/subject has consented to disclosure, or the release occurs pursuant to a statute or regulation specifically authorizing the disclosure of such information (e.g. 21 C.F.R. § 20.88 permits disclosure, under certain conditions, to state government officials).	The record may be disclosed to public after record is closed, or if the record is not closed, where the agency has decided to make a discretionary disclosure. Confidential commercial, trade secret, or personal privacy information should be redacted unless the submitter/subject has consented to disclosure, or the release occurs pursuant to a statute or regulation specifically authorizing the disclosure of such information (e.g. 21 C.F.R. § 20.88 permits disclosure, under certain conditions, to state government officials).

2. *Form FDA-483's [21 C.F.R. § 20.101(a)]*

28. When may FDA disclose the firm's response to the Form FDA-483?

The firm's response to the Form FDA-483 constitutes general correspondence and, therefore, once properly redacted, is available for disclosure to the FOIA requester (21 C.F.R.§ 20.103) at the time it is received by FDA.

3. *Warning Letters, Untitled Letters, Form FDA-483's, and Other Records Covered by 21 C.F.R. § 20.101(a)*

29. What are the general rules for FDA's disclosure of Warning Letters, untitled letters, FDA Form 483's and other records covered by 21 C.F.R. § 20.101(a), either pursuant to a FOIA request or on its own initiative?

FDA regulations at 21 C.F.R. § 20.101(a) address administrative enforcement records that are routinely prepared for disclosure to the public. For purposes of this provision, the term "public" includes the company at issue in the record. Examples of such administrative enforcement records include Warning Letters, correspondence with companies following factory inspection, FDA recall or detention requests, notices of refusal of admission of an imported product, information letters, untitled letters, Form FDA-483's furnished to the companies after factory inspection, and similar records.

These records are generally available after the first public disclosure which, as stated above, could be FDA's disclosure of the record to the inspected firm. Even though the disclosure to the inspected firm will be deemed a public disclosure, the records should be redacted of any confidential commercial, trade secret or personal privacy information prior to being further disclosed to the public. *Consideration of when the record is closed is not relevant to the release of a document covered by 21 C.F.R.§ 20.101(a) as it is for documents covered by §§ 20.101(b) and (c).*

However, slightly different rules may apply where the administrative enforcement records relate to the agency's inspection of an individual clinical investigator rather than a firm. Legal restrictions under the Privacy Act formerly precluded FDA from disclosing Warning Letters, untitled letters, and similar records absent a FOIA request. However, on October 19, 1998, FDA issued a *Federal Register* Notice (SMS to insert cite) that notified the public of its intent to alter Privacy Act System of Records 09-10-0010 for the "Bioresearch Monitoring Information System, HHS/FDA." The main purpose of the alteration was to add a new "routine use" that would allow FDA to disclose records covered by the Privacy Act to sponsors and Institutional Review Boards (IRB's) involved with studies affected by a clinical investigator's violative or potentially violative conduct without the need for a FOIA request..

The alteration became effective in late November 1998, and FDA's Office of Regulatory Affairs has set up an internal working group to facilitate the implementation of the new routine use. Until the working group's task is accomplished, FDA may continue to disclose a redacted (a clinical investigator's name need not be redacted) copy of a Warning Letter to the clinical investigator's sponsor(s) and IRB(s). The sponsor(s) and IRB(s) may be "cc'd" on the Warning Letter to the clinical investigator and FDA will send them the redacted copy of the Warning Letter.

Consider the information in "Table 2" below before disclosing an administrative enforcement record covered by 21 C.F.R. § 20.101(a).

TABLE 2. 21 C.F.R.§ 20.101(a): Administrative Record, such as a Warning Letter, Untitled Letter, or Form FDA-483, that is Routinely Prepared for Disclosure to the Public.

	On FDA's Own Initiative	FOIA Request
Redacted	Once disclosed to the subject firm, the record may be disclosed to the public, after redaction of confidential commercial, trade secret and personal privacy information.	Once disclosed to the subject firm, the record may be disclosed to the public, after redaction of confidential commercial, trade secret and personal privacy information.
Unredacted	The record may be disclosed to public after record is disclosed to the subject firm. Confidential commercial, trade secret, or personal privacy information should be redacted unless the subject firm has consented to disclosure, or the release occurs pursuant to a statute or regulation specifically authorizing the disclosure of such information (e.g. 21 C.F.R. § 20.88 permits disclosure, under certain conditions, to state government officials).	The record may be disclosed to public after record is disclosed to the subject firm. Confidential commercial, trade secret, or personal privacy information should be redacted unless the subject firm has consented to disclosure, or the release occurs pursuant to a statute or regulation specifically authorizing the disclosure of such information (e.g. 21 C.F.R. § 20.88 permits disclosure, under certain conditions, to state government officials).

4. Confidential Informant [5 U.S.C. § 552(b)(7)(D); 5 U.S.C. § 552(c)(2)][21 C.F.R. §§ 20.32, 20.64(a)(4)]

30. To what extent should personal identifiers of a confidential informant and information provided by that informant be redacted in a record?

Records or information compiled for law enforcement purposes may be withheld from public disclosure to the extent that releasing this information could reasonably be expected to disclose the identity of a confidential source. Exemption 7(D) protects both the IDENTITY of the informant and all INFORMATION provided by the informant that might reasonably be found to lead to disclosure of the informant's identity. While the utmost protection possible will continue to be afforded to confidential sources, Attorney General Janet Reno's "foreseeable harm" analysis under Exemption § 552(b)(7)(D) promotes the withholding of information only to the extent necessary to prevent source identification.

If the confidential informant requests the record, consider the following factors. Verify the identity of the requester. If the informant requester fails to provide the requested identification, and the requester is the subject of the record, use a "**Glomar**" response, or if circumstances warrant (rare), use the "(c)(2) Exclusion" [5 U.S.C. § 552(c)(2)]. By using this exclusion (which contemplates a request by a third party), FDA may treat the records as not subject to the requirements of FOIA. This exclusion should not be exercised without consulting Shari Sheehan, who will discuss the matter with OCC and DOJ's Office of Information and Privacy.

If the informant requester fails to provide the requested identification, and is not the subject of the record, but the record contains personal identifiers about the informant and/or information that would tend to reveal the identity of the informant, redact the record as you would for a member of the public. If the informant requester provides the requested identification, redact proprietary or other information that routinely would be protected from disclosure to the informant requester before releasing the record to that person. Consider sending the record by certified mail or other specialized mail service that requires the recipient to sign for the package before it is released to that informant requester. The informant requester's name should not be listed in the FOI log.

5. *Database Information [21 C.F.R. §§ 20.64 and 20.101(c)]*

31. What information can FDA release from its ORA databases that are generally related to inspections?

ORA prepares a variety of inspection-related databases and fields within each database. Examples of ORA's databases include the Compliance Achievement Reporting System (CARS), the "Organisation for Economic Co-operation and Development" (OECD) list, the Official Establishment Inventory (OEI), and the Compliance Status Information System (COMSTAT). The database might consist of both FDA-prepared information and information provided by the firm. While not an exhaustive list, set out below are examples of information that may be released.

Regarding information that FDA prepares, if the ORA database field information is derived from a document that is covered by 21 C.F.R.§ 20.101 (administrative enforcement records), refer to **Q27 and Q30** to determine the general rules for disclosure.

Status of an inspection. The status of an inspection may be reflected as, for example, "open," "pending," "unacceptable," or "not in compliance." Often FDA will convey the status of the inspection to the firm either in a Form FDA-483 or a Warning Letter. Once the firm is put on notice of the status of the inspection, FDA may disclose the "status" field in a database to the public because the firm, a member of the public, already "knows" the status of the inspection.

Status of an EIR. Unlike the *contents* of the EIR record which generally is withheld from the public under 21 C.F.R. § 20.64 until the record is considered "closed," (see **Q21**), the *status* of an EIR record is generally released. FDA routinely cites the status of an EIR as "open investigatory" if the EIR record is not closed at the time FDA processes the FOIA request.

Also, FDA generally will disclose information in a database that a reader could readily deduce even if redacted. For example, if it is readily apparent (e.g. language in the introduction, common knowledge, etc.) that the ORA database has only two statuses, such as "in compliance" or "pending," both statuses would be identifiable, even if one of them were redacted. In certain unusual circumstances, however, it may be appropriate to redact both fields. If the reader believes that this is the case, s/he should contact ORA or OCC for advice.

Central File Number. Generally, the Central File Number may be disclosed.

Updating the Database. If an ORA database is not up to date, responsive information may nevertheless be released pursuant to a FOIA request. However, the transmittal letter should have a disclaimer that the information is not up to date. FDA need not create a new record, i.e., update a field, simply to respond to a FOIA request.

32. What rules of redaction apply to the Design Control Reports?

The Center for Device and Radiological Health's Design Control Report is a "fill in the blank" questionnaire, to which the usual rules of redaction apply. Unique specifications and vendors should be deleted, as is done when the District Office releases an EIR.

33. What information about imports in the "Notice of FDA Action," or a report generated by OASIS is protected from disclosure to the public?

Redact the names of the U. S. owner/consignee and the importer of record from the Notice of FDA Action. The Notice of FDA Action is the notice generated by the Operational and Administrative System for Import Support (OASIS); it replaces the FDA Form 701 and associated notices. When providing a requester an OASIS report of an entry (one or more lines), or a line (one product) of an entry, or a summary of entry data, redact the name of the U.S. owner/consignee and the U.S. importer of record along with the quantity and value of the product. Unless the public already knows that information, FDA ordinarily considers it to be confidential commercial information, which is protected from disclosure by FOIA Exemption Section 552 (b)(4). When you respond to a request for import records (Notice, report, other data in OASIS system, etc.), the responsive record should show the appropriate Import Product Identification (IPID) number, which is made up of the U. S. Customs Entry Number, line number, along with any suffix, if present (example: 123-1234567-8/001/003/A). The IPID number is shown on the FDA Notice of Action and is listed as part of FDA's Monthly Report of Detention Actions found on the Internet. An example of the OASIS Notice of FDA Action is shown as an exhibit in Chapter 6 of the Investigations Operations Manual, and as an exhibit in Chapter 9 of the Regulatory Procedures Manual.

6...Recalls [21 C.F.R. §§ 20.64, 20.91, and 20.101(a) and (c)]

34. What information, if any, is releasable, regarding a recall and when may that information be disclosed?

Generally, FDA publicly discloses information when:

1. it issues a press release,
2. it issues the FDA Enforcement Report, or
3. it otherwise informs the public about the recall pursuant to the

criteria set out below.

A. Information that is in the public domain. FDA may disclose information deemed to be in the public domain. For example, information may be disclosed to the extent it previously has been provided to the public by the firm (see 21 C.F.R. § 20.81). A firm publicly discloses information when it notifies its customers in writing, electronically, or verbally (e.g., visits to the customer) about a recall it plans or has initiated. Before FDA discloses such information, it should obtain for its records a copy of the firm's letter to the public, the firm's written statement about the information that it gave the public, or some other reliable verification of the facts.

B. Information that is not in the public domain, but which is not protected from disclosure by a FOIA Exemption (5 U.S.C. § 552). An FDA recall request that is issued to a firm is an administrative enforcement record [21 C.F.R. § 20.101(a)]. FDA may release the recall request to the public once it is given to the firm regardless of whether the recall record is closed.

C. Information that is exempt under the FOIA, but for which FDA has the discretion to disclose and has exercised that discretion. Documents, such as an EIR or a Recall Termination Recommendation/Summary of Recall, prepared by FDA are considered "investigatory records" that are protected from disclosure under FOIA Exemption § 552(b)(7)(A). These records may be released to the public after the records are closed, subject to 21 C.F.R. § 20.64. Generally, the recall record is closed when FDA decides that no additional administrative or regulatory action is warranted. However, FDA may disclose recall records that have not been closed as a matter of Agency discretion [21 C.F.R. §§ 20.82 and 20.101(c)], including certain confidential commercial information that may be exempt from disclosure (e.g. brand name, code designation, and distribution data) to the extent necessary to make the recall effective (see 21 C.F.R. § 20.91).

ORA management determines as a matter of policy when it is appropriate to exercise the agency's discretion to disclose recall information before the record has closed. Examples of records considered for release include the 24-Hour Alert and the Recall Recommendations, that FDA prepares during the recall process. However, before disclosing such records to the public, FDA should redact any confidential commercial, trade secret, or personal privacy information, except to the extent it may be necessary to disclose certain confidential commercial information (e.g., brand name, code designation and distribution data) to effectively carry out the recall (21 C.F.R. § 20.91).

Finally, information may not be disclosed verbally that could not be disclosed in writing.

7. Injunctions [21 C.F.R. §§ 20.64 and 20.101(c)]

35. When can FDA release the EIR of a firm that is enjoined?

Generally, FDA may release the EIR when the EIR record is closed, whether or not the EIR was the basis for, or relates to, the court-ordered injunction.

8. Miscellaneous

36. Is the correspondence FDA sends to a firm during an investigation protected from disclosure to third parties on the basis that the investigation is "open?"

No. Correspondence that FDA sends to the firm during an open investigation would not be protected from disclosure to third parties under FOIA on the grounds that the investigation is still open [see 21 C.F.R.§§ 20.101 and 20.103; 5 U.S.C. § 552(b)(7)(A)]. Such records, once sent to any member of the public including the firm, are thereafter available for disclosure to third parties. However, the correspondence may need to be redacted before it is disclosed to delete any confidential commercial or trade secret information, and in some cases, to delete personal privacy information.

37. If FDA sends a firm either draft or final minutes of a meeting with that firm and the investigation remains open, can FDA protect those minutes from disclosure to third party requesters under FOIA?

No. The rationale relating to this and other administrative enforcement records (e.g., Form FDA-483's, Warning Letters) is that once these records are disclosed to any member of the public, including the firm that is the subject of the enforcement action, such records are available for public disclosure at the time such disclosure is first made [21 C.F.R. § 20.101]. However, to the extent the minutes contain proprietary information about the firm under investigation, such information would need to be redacted prior to disclosure to third parties under FOIA.

E. General

38. What does one do if he/she receives a request for non-public information from a Health and Human Services (HHS) government requester?

Because FDA is part of HHS, a request from an HHS requester is not considered a request from another federal agency under 21 C.F.R. § 20.85. FDA generally may share non-public information, including trade secrets, with an HHS requester [21 U.S.C. § 301(j)]. The names of other HHS agencies are listed at the end of this answer.

Release of information to either an HHS or non-HHS federal government requester is not a "disclosure" that would trigger release to the public under 21 C.F.R. § 20.81. At this time, and unless there is a formal FDA agreement with the requester to the contrary, there is a minor difference in procedure between responding to a request from a non-HHS requester and an HHS requester for non-public information. Regulatory Procedures Manual, Chapter 8, (August 1997) sets out the procedure for sharing information under 21 C.F.R. § 20.85 for non-HHS requesters. Unlike the non-HHS federal government requester, the HHS requester need not complete a separate confidentiality assurance form. However, in its transmittal of the information to this requester, FDA should note that trade secret and confidential commercial information are enclosed and should be safeguarded appropriately. Please notify ORA, OE, DCP, for information purposes only, when the transmittal occurs.

In addition to FDA, the agencies or offices that are a part of HHS are the Office of the Inspector General, the Administration for Children and Families, the Assistant Secretary for Aging, the Health Care Financing Administration, the Agency for Health Care Policy and Research, the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, the Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Substance Abuse, and Mental Health Services Administration and Program Support Center.

39. If there has been a grand jury indictment and there will be a trial, when will the records become releasable through FOIA?

This will be addressed on a case-by-case basis. Contact S. Sheehan at ORA's OE, DCP, (301-827-0412) to discuss.

40. Can a requester sue FDA for failure to provide a response to a FOIA request in a timely manner?

Yes, a requester might use FDA's failure to provide a response to a FOIA request within the statutory time period of twenty days as a basis for bringing a law suit against the agency in federal district court. If the requester sues FDA concerning its request, the court may allow FDA additional time to complete its

processing of the request if it can be shown that "exceptional" or unusual circumstances exist and that FDA is exercising due diligence in responding to the request. Under EFOIA [5 U.S.C. § 552(a) (6)(C)(ii)], generally having a backlog of unanswered FOIA requests is not a justification for the delay unless FDA can show that it is making "reasonable progress" in reducing its backlog. Examples of unusual circumstances might include instances when the records are contained in multiple or remote locations, when a request requires a review of a large volume of documents, or when the submitter of the information or another federal agency has to be consulted. However, every effort should be made to respond to requests within the statutory timeframe because defending such lawsuits generally requires a very large investment of time and energy by the same FDA employees involved in processing the FOIA request.

41. What should be done if a requester threatens litigation?

If a requester is threatening to sue FDA, contact the Director, FOI Staff, and one of the OCC attorneys who is familiar with FOIA issues. To minimize the likelihood that a requester will sue for failure to respond or for failure to conduct an adequate search, try to promptly respond whenever possible, and do a thorough and reasonable search in those offices and other places where responsive records are likely to be found. Also, it is important to create a good administrative record by documenting the search, especially if the search is complicated. In the event of litigation an employee may have to provide detailed information under oath about the search s/he conducted.

42. What is "discovery" in the context of litigation?

Discovery is the fact-gathering process that occurs after a lawsuit has been filed. The purpose of discovery is to provide the attorneys for the parties information about the alleged wrongdoing and the extent of damage. Information generally is obtained from an individual's statement (deposition) or answers to a series of questions (interrogatories). In cases brought against FDA by a FOIA requester, the FOIA requester is rarely granted discovery by the Court.

43. What is a Consent Decree?

A Consent Decree is an Order of the Court that reflects an agreement entered into by the parties to resolve disputed issues. Such documents are often used by FDA to require firms to come into compliance with the Food, Drug, and Cosmetic Act and the agency's regulations (e.g. seizure actions). FDA may release copies of the Decree once it has been filed with and signed by the Court.

44. How can the District Office ensure that the monthly "Pending Files/Status Report" summary it receives from HFI-35 relating to outstanding FOIA requests sent to the District Office for action is current?

Send the District Office's contact person in HFI-35 a copy of the response letter and enclosures around the middle of the month. Don't wait to the end of the month. Depending on the time the information is received, the deletion should

be reflected on the next month's Report list. If two updates go by and the information the District Office sent isn't reflected, then contact HFI-35, B. Schulman (301-827-6500).

45. What if the District Office has not received the request from HFI-35 that is noted on the "Eight Day Pending Report?"

The "Eight Day Pending Report" is a computer printout, generated and issued by HFI-35, that lists the following information: Report Date, Action Office mailing symbol, FOIA Control Number, Due Date, Requester Name, Status (such as "pending action"), and Other Action Office mailing symbols. HFI-35 uses this Report as a tracking tool for FOIA requests that it distributes. If the District Office has not received the FOIA request by the time it receives the Eight Day Pending Report, let the appropriate contact person in HFI-35 know immediately. Only by reading the request can the District Office properly give HFI-35 the information it needs. That is, the District Office should mark each item on the Eight Day Pending Report either an "A" for acknowledgment or "L for "letter of determination," and return the Report to HFI-35 at least two days before the due date.

46. Whom should the District Office contact if it does not receive a copy of the final disposition of its denial recommendation concerning a FOIA request?

Confirm with the appropriate HFI-35 contact person that it has issued the final disposition and request a copy. If the District Office does not receive the copy within 10 days from its request, please contact HFI-35's FOIA Denials officer, L. Weinstein, Esq., at 301-827-6500.

47. How does FDA treat a FOIA request for disclosure of a physical specimen such as a culture?

A physical specimen such as a culture is not a record. FOIA pertains only to records, and not to tangible, evidentiary objects. The courts have defined a record, as "...that which is written or transcribed to perpetuate knowledge," DiViaio v. Kelley, 571 F.2d 538, 542 (10th Cir. 1978). The recent Electronic Freedom of Information Amendments (EFOIA) to the statute have clarified that the definition of a "record" includes information stored in any electronic format.

48. Can FDA release copies of photographs?

Yes, however, if the photograph reveals information that would otherwise be protected by a FOIA exemption (i.e. law enforcement techniques, a firm's equipment, a legitimate privacy expectation of an employee, etc.), and the firm has not already released the photograph to the public, the photograph may be withheld.

49. Can members of the public come in to make copies of public comments submitted in response to proposed rules, or do they have to make a FOIA request?

The requester need not make a FOIA request. He or she should find out the Docket number referenced in the *Federal Register* proposed rule, then go to the Dockets Management Branch, 12420 Parklawn Drive, Rockville, Room 1-23. The requester then can look at an index according to Docket number to see what was submitted, and fill out a request form for the document he/she wants copied. Dockets will provide up to 50 pages on the spot. Requests for over 50 pages will be mailed out, usually the next day. The requester will be billed by the FOIA Office at 10 cents per page in either case.

50. Should an analytical worksheet that FDA prepares be redacted before disclosure?

The analytical worksheet that FDA prepares (also referred to as "lab analysis report," "lab report," "lab results," or "analyst worksheet"), is available upon request to any interested person, whether or not that person is directly affected by the results of the analysis. Consideration of whether the record is closed is not relevant regarding an analytical worksheet. Once disclosed to one member of the public, these records become generally available to the public [see comments 113 and 186 in 39 *Federal Register* 44602 (December 24, 1974), and 21 C.F.R. § 20.21]. Also, results of analysis are given to a person when required by statute, e.g. 21 U.S.C. § 704(d), regarding samples of food. Redaction of analytical worksheets prior to disclosure generally will not be necessary.

51. When may FDA disclose to a FOIA requester the letter that the Center Director sends a company notifying it that one or more of its applications is subject to the Application Integrity Policy (AIP)?

The Center Director's letter notifying the firm that the AIP has been invoked against an application may be released to a FOIA requester after the firm receives it, unless release of the letter would divulge the existence or other proprietary information about the particular pending application. Before release, you should redact from the letter any information that is protected from disclosure to the public by FOIA Exemption 4 (confidential commercial and trade secret information), or by Exemption 6 (personal privacy data).

52. After FDA invokes the AIP, when may it disclose to a FOIA requester the Corrective Action Plan that a firm submits?

The firm's Corrective Action Plan (CAP) is available for public disclosure at the time it is received from the firm, release of the CAP would divulge the existence or other proprietary information about the particular pending application. Before release, you should redact from the letter any information that is protected from disclosure to the public by FOIA Exemption 4 (confidential commercial and trade secret information), or by Exemption 6 (personal privacy data).

53. What documents regarding the AIP are available on the Internet?

Unlike a redacted Warning Letter, FDA does not automatically put on the Internet the redacted letter from the Center Director to the firm invoking the AIP. However, FDA has placed certain documents related to the AIP on the Internet, and they may be found at the addresses listed below.

1. 1991 Federal Register Notice: http://www.fda.gov/ora/compliance_ref/frn/fraud_ill_grat.html

2. AIP List of firms whose application(s) are subject to the AIP: http://www.fda.gov/ora/compliance_ref/aiplist.html. This is always the current list.

3. Regulatory Procedures Manual subchapter 10 on the AIP: http://www.fda.gov/ora/compliance_ref/rpm_new2/rpm10aip.html

4. Compliance Policy Guide 7150.09, Sec. 120.100, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities: "http://www.fda.gov/ora/compliance_ref/cpg/"

Another approach is to go to FDA's Home Page at http://www.fda.gov, then "Field Operations," then "Compliance References," and the documents will be listed there.

54. What does a FOIA Officer do if he or she learns that information was disclosed through FOIA in error?

Information that was not properly authorized for disclosure under FOIA should be retrieved and not further disclosed, if possible. This might occur, for example, if confidential commercial information was inadvertently disclosed. Document all steps taken to rectify the error, properly redact the document, and re-release it to the requester.

55. Should FDA deny a FOIA request for ORA's Gold Disk?

The request should be denied because it is not technologically possible to redact a CD-ROM at this time. Since the majority of releasable documents are available electronically from the FDA Home Page, FDA could direct the requester to that site.

56. Is FDA's audit criteria used in the evaluation of an FDA investigator's performance protected from disclosure?

FDA has a procedure whereby, in certain circumstances, it audits the performance of an FDA investigator. Audit criteria that identify processes, systems, and records actually checked during an inspection may be withheld from disclosure under FOIA Exemption 7(E), which protects information that: (1) "would disclose techniques and procedures for law enforcement

investigations or prosecutions..." or (2) "...would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law." [5 U.S.C. § 552(7)(E)]. If FDA's audit criteria are not already known to the public, withholding the information is justified if disclosure could reduce the future effectiveness of the criteria.

Although rarely used, the information also could be protected from disclosure under FOIA Exemption 2, 5 U.S.C. § 552(b)(2) (sometimes referred to as the "High" 2 Exemption). This Exemption provides that a record may be withheld if the information is predominantly internal and if release of the information would risk circumvention of an FDA regulation or statute or impede the effectiveness of FDA's law enforcement activities. In some cases, the Courts have held that release of agency audit guidelines have been found likely to result in harmful circumvention, and thus such guidelines were considered exempt under FOIA Exemption 2.

However, notwithstanding the applicability of those exemptions, the information should be released as a matter of agency discretion unless FDA determines that disclosure would cause the agency "foreseeable harm" to an interest protected by a FOIA exemption.

57. What documents are necessary to certify a record, and should the record be redacted? What does "authentication" mean?

Under Rule 44 of the Federal Rules of Civil Procedure, FDA should prepare an affidavit and a certificate to accompany a record that is certified as a true copy of an official FDA record. See the Regulatory Procedures Manual (August 1997), Subchapter 8 on FOIA, for an example of an affidavit or certificate. The record should be redacted of information protected from disclosure to the public by a FOIA exemption. The affidavit is the document that is attested to by the officer having the legal custody of the record. The affidavit is accompanied by a certificate that such officer has the custody. The person who completes the certificate has to have the authority to set the agency's seal to the certificate. Because the seal serves to authenticate the certificate, it is not necessary that the certificate be notarized or executed under the penalty of perjury under 28 U.S.C. § 1746. The persons authorized to release the records are listed in 21 C.F.R. § 5.23. Generally, the individual who signs the certificate should be an FDA official who is in a higher management position than the individual who signs the affidavit.

Consider the following placement of the documents: The record is on the bottom, then the affidavit, and the certificate is on top. The package usually is bound by a red ribbon to which a gold star with the HHS emblem is affixed, and embossed with the seal. The fee is $10 per certification.

Generally, the term "authentication" means the act of giving legal authenticity to a record so it might be legally admissible in evidence (Black's Law Dictionary). Often a request for FDA to authenticate a record is one in which the requester provides FDA a record and asks FDA to state that the document the requester provided is an exact replicate of an FDA record. Rather than doublechecking the wording in the incoming document (and possibly overlooking an important point), FDA generally retrieves its own copy of the record in issue and certifies it as a true copy instead.

58. Should a record disclosed in response to a subpoena be redacted?

Yes, redact the record of information that is protected from disclosure to the public by a FOIA exemption. A court might issue an Order compelling FDA to disclose the information that was deleted. If that occurs, notify OCC for advice.

Attachment: Certification of Identity

Certification of Identity. In accordance with 21 C.F.R. § 21.44 personal data sufficient to identify the individuals submitting requests by mail under the Privacy Act of 1974 (5 U.S.C. § 552a), is required. FDA also is using this form to obtain personal data sufficient to identify individuals submitting requests by mail under the Freedom of Information Act, 5 U.S.C. § 552. The purpose of this solicitation is to ensure that the records of individuals who are the subject of Food and Drug Administration (FDA) systems of records or other FDA records are not wrongfully disclosed by FDA. Furnishing this information is voluntary. Failure to furnish this information will result in no action being taken on the request. However, FDA will need sufficient information to verify the identification of the requester before it discloses the requested record. False information on this form may subject the requester to criminal penalties under 18 U.S.C. § 1001 and/or 5 U.S.C. § 552a(i)(3).

Full Name of Requester[1]: _____

Current Address: _____

Date of Birth: _____

Place of Birth: _____

Social Security Number[2]: _____

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that I am the person named above, and I understand that any falsification of this statement or on this form is punishable under the provisions of 18 U.S.C. § 1001 by a fine of not more than $10,000 or by imprisonment of not more than five years or both, and that requesting or obtaining any record(s) in a Privacy Act system of records under false pretenses is punishable under the provisions of 5 U.S.C. § 552a(i)(3) by a fine of not more than $5,000.

Signature[3] _____ Date _____

Optional: Authorization to Release Information to Another Person

This form is also to be completed by a requester who is authorizing information relating to himself or herself to be released to another person.

Further, I authorize the FDA to release the following information relating to me: _____ to the person listed below:

_____

[1] Name of individual who is the subject of the record sought.

[2] Providing your social security number is voluntary. You are asked to provide your social security number only to facilitate the identification of records relating to you. Without your social security number, the Agency may be unable to locate any or all records pertaining to you. (Executive Order 9397.)

[3] Signature of individual who is the subject of the record sought.

SECTION IV

FDA FOI Procedures

Section IV

FDA FOI Procedures

In section IV This section contains the following procedures

Information Disclosure Procedures, Freedom of Information Act (FOIA)

PURPOSE AND SCOPE

The purpose of this subchapter is to provide procedures to implement the Freedom of Information Act (FOIA). These procedures apply to Food and Drug Administration (FDA) employees and all FDA organizational components. This subchapter is intended to supplement Department of Health and Human Services' (DHHS) and FDA's FOIA preambles and regulations. For greater detail, read DHHS regulations implementing the FOIA, 45 C.F.R. Part 5, and FDA's regulations, 21 C.F.R. Part 20 and the preambles to FDA's regulations at 39 Federal Register 44602 (December 24, 1974) and 42 Federal Register 3094 (January 14, 1977). This subchapter has been adapted from Staff Manual Guide 2460.07, and includes information related to several provisions of the "Electronic Freedom of Information Amendments of 1996" (H.R. 3802) ("EFOIA").

AUTHORITY

1. 5 U.S.C. 552, as amended by Public Law 99-750, Sec. 1801-1804, and the "Electronic Freedom of Information Amendments of 1996" (H.R. 3802)
2. 45 C.F.R. Part 5
3. 21 C.F.R. Part 20 (Exhibit 8-1; Title 21 References to FOIA)
4. Executive Order No. 12,600
5. Preambles to 39 Federal Register 44602 (December 24, 1974) and 42 Federal Register 3094 (January 14, 1977)

DEFINITIONS

Freedom of Information Act (FOIA): Section 552 of Title 5, United States Code, as amended by Public Law 99-750 and the "Electronic Freedom of Information Amendments of 1996" (H.R. 3802).

Acknowledgement Letter: A letter which notifies the requester that the request has been received and gives the FOIA control number. The control number is assigned by the FOI Staff when the request is logged in upon receipt. This letter does not end the statutory time requirement. This letter should only be used when a determination has not been made to release or deny the record within ten (effective October 2, 1997, twenty) days. (Exhibit 8-2) (See Letter of Determination below.)

Appeal: Any requester has the right to appeal a denial of records to higher authority. The appeal authority for FDA is the Assistant Secretary for Public Affairs, DHHS.

Appeal Justification Memorandum: Upon notification that the denial of records requested under FOIA has been appealed to DHHS, the component FOIA Officer should be asked to prepare a memorandum to the FOI Staff providing sufficient explanation and justification to convince the Department that the FDA denial should

be upheld. The memorandum should be accompanied by copies of the denied information for Department review if needed.

Component FOIA Officers: Designated FOIA Officers within each major organizational component in FDA, including each Center, District, and Office of Associate Commissioner who is the responsible individual for all FOIA activities within the component.

Confirmation of Amended Request: This letter transmits documents in response to a requester's amended FOIA request. The amendment reflects the requester's wish to receive that portion of the original request that is releasable.

Denial Letter: A letter responding to a FOIA request by partially or wholly denying access to, or copies of, requested record(s). The letter must be signed by the Associate Commissioner for Public Affairs (ACPA), and must cite the appropriate sections of the FOIA and implementing regulations to support exemption from disclosure.

FOIA Officers: Any responsible FDA employee whose experience and training enable him/her to process FOIA requests.

FOIA Request: Any request for existing records not prepared for routine distribution to the public. Requests must at least "reasonably" describe the requested records. Documents must be described, but they do not need to be specifically identified.

Form: Within the context of the EFOIA, FDA has interpreted the term "form" to mean the defined medium the record is physically incorporated in/on, such as, paper, floppy diskette, CD-ROM or microfiche.

Format: Within the context of the EFOIA, FDA has interpreted the term "format" to mean the type of electronic record and the specific program used to generate and/or produce the record, such as wordprocessing (MS Word, WordPerfect, ascii text), or spreadsheet (Lotus 1-2-3, MS Excel).

Letter of Determination: A letter responding to a FOIA request stating the requested record will be disclosed. This letter ends the statutory time requirement. (Exhibit 8-3). (See Acknowledgement Letter above.)

Record: A "record" means any handwritten, typed, or printed document (such as memorandum, book, brochure, study, writing, draft, letter, transcript, and minutes) and documentary material in other forms (such as punchcard; magnetic tape, card, or disc; paper tape; audio or video recording; map; photograph; slide; microfilm; and motion picture). It does not include an object or article such as an exhibit, model, equipment, and duplication machine or audiovisual processing material. It does not include a book, magazine, pamphlet, or other reference material in formally organized and officially designated DHHS libraries, where such material is available under the rules of the particular library. The EFOIA [5 U.S.C. 552(f)] defines a "record" to be "... an agency record subject to the requirements of this section when maintained by an agency in any format, including an electronic format."

GENERAL CONSIDERATIONS

GENERAL

FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in regard to trade secrets, and the need for FDA to promote frank internal policy deliberations and to pursue its regulatory activities without disruption. This policy includes disclosure of records where it would be in the public interest to do so, even though they might otherwise be withheld under strict interpretation of the FOIA. This section sets out important general information procedures to implement the FOIA.

1. All requests for FDA records should be sent in writing to the Freedom of Information Staff ("FOI Staff") (HFI-35), 5600 Fishers Lane, Rockville, MD 20857. FOIA requests which are addressed to other FDA organizational components should be immediately sent by messenger or faxed to the FOI Staff to be logged in.
2. A verbal request for a document should be reduced to writing before responding.
3. If any document or information is disclosed in an authorized manner to any member of the public, it must be made available to all members of the public, except as provided for in 21 C.F.R. 20.21 (a) and (b), 20.88, and 20.89,
4. A response to a request should be issued within ten (effective October 2, 1997, twenty) working days from the date of receipt by the FOI Staff. The response may take the form of (1) a letter of determination, (2) a denial letter, (3) a letter invoking the 10-day extension, (4) release of the requested records by the component FOIA Office, (5) a predisclosure notification letter, or (6) an acknowledgement letter. (The last two letters do not end the statutory time requirement).
5. The FOIA does not require a determination of disclosure to be given in response to a request for a record not in the possession of FDA or not yet in existence at the time the request is received. FDA should, however, respond as fully as reasonably possible to such requests. In response to a request for a record which is not yet completed, indicate that the record is not complete and offer (if possible) an estimate of when the record will be completed, so that it can be requested at that time. Do not offer to provide the record when it is completed.
6. Requests that specific records be automatically and regularly sent through the FOIA process as they are created should not be fulfilled.
7. The authority and responsibility for granting most FOIA requests are vested in the FOIA Officer of the organizational component maintaining the records. Discretionary disclosure (21 C.F.R. 20.82) can only be made by Associate and Deputy Associate Commissioners as authorized by 21 C.F.R. 5.23. Disclosures to other federal government departments and agencies (21 C.F.R. 20.85) can be made by those persons, plus the Director and Deputy Director, Office of Regulatory Affairs (ORA), Office of Enforcement (OE), and the Director, Division of Compliance Policy (DCP), ORA, OE, also as authorized by 21 C.F.R. 5.23.

PRIVACY ACT

All Privacy Act (PA) records are covered by FOIA, but not all FOIA records are covered by PA. The PA covers a record that is maintained by FDA in a system of records and that contains information about an individual, including the individual's name or other personal identifier (e.g., social security number). A system of records is one in which information is indexed or retrieved by the individual's name or other personal identifier. The fact that records could be retrieved by way of an individual's name or other personal identifier does not make the records a PA system of records. The relevant inquiry is whether the records are in fact retrieved in that manner. Additional information is set out below.

1. Generally, a first-party request (a request by an individual for his or her own records) is processed under both FOIA and the PA. Mark the request, "Privacy Act Request," and forward it, with a notation of where the record may be found, to FDA's PA Officer, who is the Director, FOI Staff, Office of Public Affairs (HFI-30). FDA's PA Officer will determine if the request should be processed as FOIA, PA, or both, and advise the FOIA Officer. Generally, the record should be disclosed unless the information is covered by an exemption under both the FOIA and the PA.
2. A third-party FOIA request for records contained in a PA system of records goes through the same process and review as any other FOIA request. The component FOIA Officer should either provide the requested documents or submit a denial recommendation to the FOI Staff if a FOIA exemption applies. Such records are subject to the same disclosure procedures. Disclosures pursuant to FOIA do not require the individual's consent. In other words, if there is no FOIA exemption prohibiting disclosure, then the records will be released, subject to redaction of exempt information.
3. Employees' requests for access to records contained in their Official Personnel Folders or similar files maintained by the Division of Human Resources Management should be sent to the Director, Division of Human Resources Management (HFA-400), unless the records are maintained in a district satellite personnel office.

REQUESTS THAT ARE PROCESSED OUTSIDE OF THE FOIA PROCEDURES

The following requests for records are not considered FOIA requests and are processed outside the FOIA procedures:

1. A request from a Congressional Committee, Subcommittee or the General Accounting Office. This request is controlled and responded to by the Office of the Associate Commissioner for Legislative Affairs.
2. A request from an official from a federal government agency (21 C.F.R. 20.85). Direct these requests to ORA, OE, DCP, HFC-230. (See RPM, Chapter 8, "Sharing Non-Public Information with Federal Government Officials".)
3. A request for non-public information from an official from a state or local government (21 C.F.R. 20.88) or foreign government agency (21 C.F.R. 20.89)

that performs counterpart functions to FDA. This is controlled and responded to by either the district office or the Center, depending on the circumstances. See RPM, Subchapter 8 (state and local) and RPM Subchapter 8 (foreign) for further information.

4. A request for a record that normally is prepared for public distribution, such as press releases, FDA Fact Sheets, information brochures ("We Want You To Know About FDA"), speeches, Congressional testimony, etc. If these documents are on FDA's Home Page (Internet), direct the requester to the appropriate website it possible. Otherwise, such records should be provided promptly to any requester, without reference to the FOIA, without referral to the FOI Staff, and without collecting any fees.
5. A request for verbal information only. The FOIA does not require the creation of new records to respond to a request. Therefore, a request for verbal information is not a FOIA activity. This inquiry should be responded to promptly, without referral to the FOI Staff, as part of FDA's effort to be responsive to the public. FOIA provisions regarding disclosability of information, e.g. confidential commercial, trade secret, etc., apply to information given verbally.
6. Testimony. A request for testimony of a current FDA employee (21 C.F.R. 20.1) should be directed to ORA, OE, DCP, HFC-230. See RPM, Chapter 8, "Testimony," for further information. Depending on the circumstances, FDA may deny a request for testimony, but suggest that it become a FOIA request for certified records (see "Special FOIA Requests" below).

RESPONSIBILITIES

RESPONSIBILITIES OF THE FOI STAFF

1. General

   The FOI Staff should:

   A. provide advice and guidance on FOIA policies and procedures to FDA staff and members of the public,
   B. serve as the FDA focal point for the receipt, control, coordination, and processing of all FOIA requests, and prepare for release those requested records maintained by the FOI Staff,
   C. ensure that each component of FDA has designated a "component FOIA Officer" to respond to FOIA requests,
   D. maintain staff manuals, indexes, warning letters, computer printouts, and other records which are to be on display for public review (Exhibit 8-4),
   E. maintain a file of all FOIA requests and FOIA responses (including copies of records sent), and dispose of these files in accordance with 21 C.F.R. 20.31,
   F. compile and prepare reports on FOIA activity in FDA,
   G. coordinate the preparation of a multiple-component response by either gathering the necessary records in its possession or by designating one or more appropriate component FOIA Officers to do so. When transmitting a copy of the FOIA request to component FOIA Officers, the FOI Staff should indicate date by which

either the component's determination of disclosure or the disclosable records should be forwarded to the FOI Staff,

H. draft denial letters for requests to which it responds, and review draft denial recommendations and predisclosure notification disagreement letters prepared by component FOIA Officers. The FOI Staff should ensure that the Office of Chief Counsel (OCC) concurs with the denial letter before the ACPA signs it, and

I. process appeals by serving as liaison between FDA and PHS and coordinate the FDA response to an appeal.

See "Administrative Procedures" and "Operating Procedures" for additional responsibilities of the FOI Staff.

2. FOIA Requests Initially Received by the FOI Staff

When the FOI Staff initially receives a FOIA request, it should:

A. log the request, showing the date received by the FOI Staff as the official date of receipt,

B. contact requesters to clarify FOIA requests which are vague, confusing, or inordinately extensive. This does not preclude a component FOIA Officer from also contacting the requester,

C. if the requested records are maintained by the FOI Staff, locate them and respond to the requester,

D. if the requested records are not maintained by the FOI Staff, assign and promptly transmit the FOI request to the component FOIA Officer for action, and

E. regularly notify each component FOIA Officer of the pending request assigned to that component, and send letters of determination or acknowledgement letters on instruction from the component FOIA Officer.

3. Special FOIA Requests

A. Request Related to FDA-Originated Information or Other FDA Records.

(1) Certified documents. The FOI Staff should forward to the appropriate FDA component, a request for a certification of a document. The component official (see 21 C.F.R. 5.22) authorized to certify should certify the responsive documents. A component is responsible for preparing an Affidavit and Certificate (Exhibits 8-5 and 8-6), responding to the requester, and sending the FOI Staff copies of the response and these documents.

(2) Testimony. A Subpoena Duces Tecum (a legal request for documents) or any other request for testimony as a record, e.g., an affidavit rather than verbal testimony, is not handled as a routine FOIA request. Such a request should be forwarded to ORA, OE, DCP (HFC-230). After consulting with the requester, DCP will advise the component FOIA Officer when and if the request will be handled as a FOIA request. This request may involve a certified record. See Chapter 8, "Testimony," for further information.

(3) Multi FDA-component requests. The FOI Staff may coordinate the response when the records overlap and are located in more than one FDA component.

(4) Documents originated by foreign government. The FOI Staff should determine the appropriate component to provide information obtained from either a foreign government or its employee that has been reduced to writing by FDA, or a record from a foreign government.

B. Request Related to non-FDA Information or Records.

The FOI Staff should send to the appropriate DHHS or non-DHHS agency for issuance, a FOIA request that involves:

(1) records in other divisions of DHHS or agencies of the PHS,

(2) records that either originated or are concerned primarily with a non-DHHS federal government agency. However, on a case-by-case basis, the FOI Staff may recommend that the requester submit its request directly to the non-DHHS agency.

The requests described above may involve coordination within as well as outside of FDA. Therefore, if the request was sent initially to the component FOIA Officer and the component has all or part of the responsive records, the component FOIA Officer should:

(1) not send any records to the requester,

(2) if requested by the FOI Staff, notify the requester that the request will be handled by either another office within FDA, or by another office within or outside DHHS, as appropriate,

(3) send two copies of all records responsive to the request to the FDA FOI Staff. The records should be clearly identified and indexed as releasable, partially releasable, and deniable with citation of the appropriate FOIA exemptions noted. When any deletion is to be made, each deletion should be bracketed in pencil, and

(4) list chargeable fees.

Exceptions should be handled on a case-by-case basis.

RESPONSIBILITIES OF A COMPONENT FOIA OFFICER

1. General

The component FOIA Officer should:

A. provide internal direction and guidance to the component on FOIA policies and procedures,

B. direct the search, review, and determination regarding disclosure of requested records,

C. in a timely manner or by the specified due date, respond to the FOI Staff's requests for information, or advise them whether requested records are disclosable,

D. prepare and issue the initial predisclosure notification letter, send the FOI Staff a copy and monitor and process the responses (see "Predisclosure Notification," in this subchapter),

E. recommend denial of records or portions of records, accompanied by an explanation of the circumstances, and a citation of the appropriate exemptions,

F. consider requests, which include requests for waivers or reductions of fees, referred by the FOI Staff (see "Waiver of Fees," in this subchapter),
G. contact the requester to clarify FOIA requests which are vague, confusing, or inordinately extensive,
H. locate the requested records within the component,
I. determine whether the requested records are disclosable,
J. prepare the records for release, delete all non-disclosable material, and release the responsive documents. However, if prepayment of fees is necessary, neither the preparation nor release of the record is required prior to notification by Division of Financial Management (DFM) that payment has been received,
K. provide additional justification in response to the appeal of a denial, accompanied by clearly identified and indexed copies of the records in question when necessary, and
L. assist the OCC if a FDA decision to deny records results in litigation by preparing documentation necessary to defend such actions.

2. FOIA Requests Initially Received by the Component FOIA Office

All FOIA requests should be addressed to the FOI Staff. If a requester sends a FOIA request to a component other than the FOI Staff, the component FOIA Officer should send the request to the FOI Staff so it can be logged in and processed according to routine procedures unless the request is for information that is clearly disclosable (i.e., either contains no non-public information to be purged or the non-public information has been redacted), readily available, and for which prepayment is not necessary. In that case, the component FOIA Officer may release the information and then send a copy of the request, the response, and if appropriate, a copy of the records to the FOI Staff, noting the name and address of the requester, and the charges.

Send a request for information listed in "Responsibilities of the FOI Staff," item 3, to that office. In that case, if the records are not in the possession of the component, indicate where they might be found. Do not respond to the requester.

RESPONSIBILITIES OF EACH FDA COMPONENT

Each major organizational component should:
1. designate a component FOIA Officer and an alternate to act in his or her absence, and
2. ensure that all employees within the component are made aware of FOIA policy and procedures.

RESPONSIBILITIES OF THE DIVISION OF FINANCIAL MANAGEMENT (DFM)

The DFM should:
1. receive all payments submitted in relation to FOIA requests, and
2. promptly notify the FOI Staff of payment.

RESPONSIBILITIES OF THE ASSOCIATE COMMISSIONER OF PUBLIC AFFAIRS (ACPA)

The ACPA should:

1. make determinations to waive or reduce fees,
2. make determinations of confidentiality in response to a request for pre-submission review of records voluntarily submitted to FDA (see "Requests for Pre-Submission Review," in this subchapter), and
3. if appropriate, sign a denial of a request for a record.

RESPONSIBILITIES OF FDA EMPLOYEES

All FDA employees should promptly refer any oral or written FOIA request to their component FOIA Officers for advice on handling.

OPERATING PROCEDURES

DISCLOSABILITY (REDACTION, PURGING) AND DENIAL ISSUES

1. Redaction Issues

It is the responsibility of the FOIA Officer to delete the following information:

A. trade secrets,
B. commercial or financial information that is confidential,
C. names and other identifying information about patients, research subjects, third parties, etc., and
D. information that reflects deliberative process or any other information protected from disclosure because it meets not only appropriate parts of FOIA Exemption 5 or 7, but would foreseeably harm FDA's interests protected by that exemption. Refer to the October 4, 1993, FOIA memorandum prepared by Attorney General Janet Reno for further information.

2. Records Disclosed with Minor Deletions

A record that contains both disclosable and nondisclosable information and that requires only minor deletions of information, may be redacted, the remaining record disclosed and a copy sent to the FOI Staff. The component FOIA Officer should not prepare a denial recommendation unless the requester appeals the response. The letter accompanying the redacted record must contain the following language:

"In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the record(s) indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address, (insert the address for the FOI Staff). Should FDA then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal."

3. Denial Recommendations for Records with Other than Minor Deletions

   If the redactions:
   A. are not considered minor,
   B. involve disclosable and nondisclosable information in a record that are so inextricably intertwined that it is not feasible to separate them,
   C. would compromise or impinge upon the nondisclosable portion of the record, or
   D. are substantial, then, except for the district office component FOIA Officer, send the FOI Staff the information set out below. A district office component FOIA Officer, should send the information to DCP, HFC-230. Send,
      (1) a memorandum marked "Recommended for Denial," that identifies each record determined to be nondisclosable, the relevant FOIA exemption, and the reason why the document or information should not be disclosed,
      (2) copies of the purged disclosed documents, and
      (3) a listing of the documents that are recommended for denial in full. Do not send copies to the FOI Staff unless requested (this would occur if the requester wanted to see the deleted information).

4. Denial Letters

   The FOI Staff prepares a draft denial letter based on the component FOIA Officer's recommendation, requests OCC concurrence of the recommendation, modifies the letter if OCC recommends, obtains ACPA signature, issues the letter, and sends a copy to the component FOIA Officer.

5. Issues Related to Electronic FOIA

   FDA must make available to the public by "electronic means" records created by FDA on or after November 1, 1996. Please create and keep documents in electronic forms and formats. On March 28, 1997, the ACPA, OCC, and Deputy Commissioner for Management and Systems issued a memorandum to FDA Senior Staff, District Directors, FOIA Officers, and the FDA EFOIA Task Force that set out the steps FDA had taken to that date to implement the EFOIA provisions. Highlights of that memorandum are set out below. Effective March 31, 1997, under EFOIA, the FOI Officer:
   A. should send to the FOI Staff, for inclusion in the public reading room, a copy of any document that is disclosed in response to a FOIA request and that FDA determines has become or is likely to become the subject of subsequent (i.e., three or more) requests for substantially the same record,
   B. must honor a requester's specified choice among existing forms of a requested record and make "reasonable efforts" to disclose a record in a different form or format when that is requested and the record "is readily reproducible" in that new form or format (see "Definitions," regarding "form" and "format"),
   C. must compile and maintain statistics on form/format requests: such as the specific form or format specified in the request, whether the request was for a form/format

in which the component already maintained the record, whether the request was complied with; if not, why not, and if so, in what form/format,

D. must advise his or her component to make a reasonable effort to search for requested records by automated means, except where doing so would significantly interfere with the operations of FDA's automated information systems. What constitutes "reasonable" and "significantly interfere" depends on the particular set of circumstances involved, and

E. if records are released to a FOIA requester with deletions, must indicate the amount of deleted information at the place in the record where the deletion is being made, if it is technically feasible to do so.

6. Miscellaneous Issues

A FOIA Officer should:

A. be aware that certain software that a FOIA Officer might use may not totally erase information that has been deleted, so that a recipient could "undelete" redacted information,

B. send a requester the best copy that can be made of a disclosable but legible record, and note in the response its poor quality. The FOIA Officer should not attempt to reconstruct the record,

C. in addition to the information in the section, "Privacy Act," consider the following information when an individual or organization requests a record which contains confidential information concerning the requester (e.g., a firm requesting a copy of an EIR of which it is the subject and no legal action is being contemplated; a person requesting his own medical record, etc.):

(1) if the document requested is an EIR, determine if the requester is entitled to receive a copy outside of the FOIA process. See Field Management Directive No. 145, effective April 1, 1997,

(2) since confidential information obtained from and related to the requester that is in a record is not considered to be publicly disclosed when it is released to the subject of the record (i.e., the requester), disclose the requested record without purging that information,

(3) redact confidential commercial, trade secret, or other non-public information that is protected by a FOIA exemption,

(4) ensure that the letter accompanying the records sent to the requester contains the following paragraph:
"As you will note, the enclosed records contain certain business or personal information which is disclosable only to you or your firm. Copies of these records should be disclosed to other requesters only after thorough review and deletion of those portions which are not disclosable to the general public,"

(5) after disclosing the record, send the FOI Staff copies of the request and purged documents, if any. Do not send the FOI Staff a copy of an unpurged document; list the document and state why the copy is not attached,

D. if the requester has used the term "disclosable" in his or her request, determine if he or she understands its meaning, and inform the requester when there are no disclosable records on a requested subject. This arises when a requester specifies

"all disclosable information," with the understanding that a denial is not necessary even when there are no records that can be disclosed on the requested subject. It is important that the requester understands the use of these terms,

E. if a requested record is not disclosable (e.g., an EIR when the investigation is still open), inform the requester and inquire if he or she is interested in narrowing the request to only those documents which are disclosable (e.g., the 483, purged if necessary). Explain to the requester that by narrowing the request in this way he or she would not receive a denial letter from FDA with instructions on how to appeal. If the requester agrees to modify the original request by indicating that he or she is interested in receiving only that which is disclosable, the FOIA Officer should document the amended request. The FOIA Officer then may send the requester the disclosable information (Exhibit 8-7).

If the requester does not narrow the request, send him or her whatever information is disclosable and prepare a denial recommendation memorandum. In the denial recommendation, state that the requester was given the option to narrow the request, but declined to do so.

ADMINISTRATIVE PROCEDURES

TIME FRAME FOR RESPONSE

The following information should be considered when preparing a response:

1. Effective October 2, 1997, FOIA requests must be responded to within twenty, rather than ten, working days from the date received by the FOI Staff. This requirement may be met by sending either the record, a denial letter, or a letter of determination concerning disclosure of the record.
2. In unusual circumstances, the FOI Staff may extend the time for sending the letter of determination by an additional ten working days.

REQUESTS FOR PRESUBMISSION REVIEW FOR CONFIDENTIALITY OF VOLUNTARILY SUBMITTED DATA OR INFORMATION (21 C.F.R. 20.44)

The validity of FDA's regulations concerning pre-submission review has been called into question by Teich v. Food and Drug Administration, 751 F.Supp. 243 (D.D.C. 1990). Therefore, any request for presubmission review for confidentiality should be brought to the attention of the FOI Staff Director, who will confer with OCC. Please respond to the requester only at the direction of the FOI Staff.

PREDISCLOSURE NOTIFICATION (P.N.)

Executive Order (E.O.) 12,600 of June 23, 1987, and 21 C.F.R. 20.61 requires notification to a submitter of records containing confidential commercial or trade secret information prior to disclosure of that information in response to a FOIA request in certain circumstances. Consider the following procedures below regarding predisclosure notification.

1. Predisclosure notification may be appropriate if:

   A. the submitter designates in writing part or all of the information in the records as exempt from disclosure under FOIA Exemption 4 (any such designation expires ten years after the records are submitted to the Government), or
   B. FDA has substantial reason to believe that information in non-designated records could reasonably be considered protected from disclosure under Exemption 4.
2. The notice requirements of this E.O. do not pertain to:
   A. a record created by FDA,
   B. a record that FDA has determined should not be disclosed,
   C. information that has been published or has been officially made available to the public,
   D. information for which disclosure is required by a statute other than the FOIA, or
   E. narrow classes of records for which disclosure under FOIA is required by a regulation, issued after notice and comment. In this case, however, a submitter may still designate records which may require the predisclosure notification procedures.
3. When a request is received for records which require P.N., the FOI Staff should forward the request to the component FOIA Officer. The component FOIA Officer should send an initial letter (Exhibit 8-8) to the submitter to inform him/her about the P.N. procedures and time limits for submission and consideration of objections to disclosure. This letter should include a copy of the request and copies of the records which require the P.N. The submitter has five working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for objections. The component FOIA Officer should send copies of this letter to the requester and to the FOI Staff.
4. If the component FOIA Officer agrees with the submitter's objections, the records should be routinely processed, i.e., either send the record with deletions or prepare a denial recommendation.
5. If the component FOIA Officer does not agree with the submitter's objections, the following procedures apply:
   A. The component FOIA Officer should draft a P.N. disagreement letter (Exhibit 8-9) for the signature of the FOI Staff Director notifying the person who submitted or provided the records in writing of FDA's final determination to disclose and the reason(s) for disclosure. The letter should provide five days from receipt of notification within which to institute suit in a United States District Court to prevent disclosure.
   B. The FOI Staff should consult OCC before issuing the letter.
   C. A copy of the P.N. disagreement letter should be sent to the requester.
6. If suit is brought, the record(s) should not be disclosed until the matter is determined in the courts. If suit is not brought, the record(s) should be disclosed.
7. If the submitter either does not object or fails to object within five working days after receipt of the P.N. letter, the records should be disclosed and a memorandum written to document the release.

FEES, BILLING, PREPAYMENT AND COLLECTION ISSUES

FEES

The amount of fees FDA should charge to respond to a FOIA request is determined by the factors set out below.

1. The FOI Staff should determine the appropriate category of requester at the time a request is logged, based on the following categories:
   A. Commercial Use Requester (Type "C")
      If the request is for commercial use, fees should be charged for the costs of search, review, duplication, and other costs such as computer costs.
   B. News Media and Educational and Scientific Institutions (Type "N")
      If the request is from: (1) an educational institution or a non-commercial scientific institution, or (2) a representative of the news media which includes the trade press, fees should be charged only for duplication, except that there is no charge for the first 100 pages of duplication.
   C. Other Requesters (Type "O")
      If the requester is not the kind described by paragraphs 1.A. and 1.B., fees should be charged only for search and duplication, except that there is no charge for the first two hours of search and the first 100 pages of duplication.

SCHEDULE

1. Searching for Records

   "Search" means looking for records responsive to a request and includes reading and interpreting a request.
   A. The FOI Staff should assess each eligible requester (Type "C" and Type "O") a standard agency charge for reading and interpreting a request. In addition, the FOI Staff should deduct the charge for up to two hours search if the requester is entitled to this deduction (Type "O") when invoiced.
   B. In 1996, the fee scheduled had been modified. The charge for search is $14 per hour for GS-1 through GS-8, $28 per hour for GS-9 through GS-14 and $51 per hour for GS-15 and above. Charges should be rounded to the nearest 15 minute increment. Calculations are based on hourly salaries for the Washington Baltimore/Rockville headquarters area (plus 16%) but are to be used nationwide.
   C. Search fees may be charged if the records found are exempt from disclosure, or even if no records are found.

2. Reviewing Records

   "Review" means examining the records to determine what portions, if any, may be withheld, and any other processing time that is necessary to prepare the records for release. The charges for review time are at the rates given in item 1.B.

3. Copying Records

   Charge ten cents per copy of each standard-size page; photocopying odd-size pages (such as punch cards or blueprints) or reproducing other records (such as magnetic tapes, microfilm, or microfiche)--actual cost of the operator's time at the rates given in item 1.B., plus the cost of operating the machine and the material used. The FOI Staff should deduct the charge for 100 pages if the requester is entitled to this deduction (Type "N" and Type "O") when invoiced.

4. Certification or Authentication of Records

   Charge $10 per certification or authentication.

5. Compiling Computerized Records

   Charge the actual cost to obtain records including computer search time, runs, printouts, and time of computer programmers and operators, or other employees at the rates given in item 1.B.

6. Mailing

   Charges cannot be made for regular mail. Actual cost should be charged for special methods such as Express Mail.

WAIVER OF FEES

Consider the following factors when a wavier of fees is requested.

1. A waiver or reduction of fees should not be considered unless asked for by the requester preferably in the original FOIA request. If the estimated charges will exceed $250, do not compile responsive records until the FOI Staff makes a decision about the waiver or reduction.
2. If a waiver or reduction of fees is requested, no charge should be made for records requested if disclosure is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and it is not primarily in the commercial interest of the requester. Further information is in 45 C.F.R. 5.45 and in the fee waiver statement issued by the Department of Justice on April 2, 1987.
3. A request for a waiver or reduction of fees can only be granted by the ACPA.
4. When a request for waiver is received and the charge to respond to the request is $250 or less, the FOIA Officer should:
   A. send the material and include the following statement in the response letter: "Your request for waiver of fees will be considered by the Associate Commissioner for Public Affairs," and
   B. forward a copy of the letter and the purged records to the FOI Staff.
5. When the request for waiver is received and the charge to respond to the request exceeds $250, the FOIA Officer should:
   A. not send the material to the requester, but

B. send a memorandum with the estimated charges and the waiver recommendation to the FOI Staff.

6. Whether or not the charge exceeds $250, the FOI Staff should:
   A. consider the waiver request,
   B. contact the requester if more information is needed,
   C. if needed, request a waiver recommendation from the component FOIA Officer, and
   D. draft a waiver response letter for the ACPA.

BILLING AND PREPAYMENT

The FOI Staff handles billing issues. The following considerations are relevant to billing and prepayment.

1. Regulations provide for aggregating the costs for requests made by the same person or organization or related persons or organizations on a periodic basis. The FOI Staff should aggregate charges and bill the requesters if the monthly total is more than $15.
2. Prepayment is necessary if: (A) the estimated fee exceeds $250, (B) the fee is over the limit specified by the requester, and/or (C) the requester has failed to pay previous bills.
3. If prepayment is necessary, the component FOIA Officer:
   A. should neither compile nor disclose responsive records until the payment is received, and
   B. may send the requester a letter requesting payment of estimated charges or ask the FOI Staff to send an invoice requesting payment.
4. If prepayment is not necessary:
   A. send the material,
   B. do not invoice, and
   C. assess all charges. Do not deduct 100 pages for duplication and/or two hours search even if the requester is entitled to them. The deduction will be done when invoiced by the FOI Staff. Inform the requester as follows:

      "The following charges may be included in a monthly invoice:

      Reproduction _____
      Search _____
      Review _____
      Other _____
      Total: $

      The above total may not reflect final charges for this request. Please do not send payment unless you receive an invoice for the total monthly fee."
5. DFM should notify the FOI Staff of receipt of prepayment. In the event that the individual cancels the request, the FOI Staff should notify the component FOIA Officer.
6. If prepayment is not received by the date specified in the letter or invoice, assume the requester is no longer interested in purchasing the records. The FOI Staff should notify the component FOIA Officer accordingly.

CHECKS

Payment should be made by check or money order payable to the Food and Drug Administration and sent directly to the Accounting Branch (HFA-121), 5600 Fishers Lane, Rockville, MD 20857.

Exhibit 8-1

TITLE 21 REFERENCES TO FOIA

Exhibit 8-2

ACKNOWLEDGEMENT LETTER

(Insert Requester's Address) (Date)
In reply refer to:

Dear Requester:

This is to acknowledge receipt of your request for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

(Insert description of document)

We will respond to your request as soon as possible. Pursuant to Departmental regulations, applicable charges will be assessed.

All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

BETTY B. DORSEY
DIRECTOR, FREEDOM OF
INFORMATION STAFF

(301) 443-1813

Enclosures:
as indicated

Exhibit 8-3

LETTER OF DETERMINATION

(Insert Address of Requester) (Date)
In reply refer to:

Dear Requester:

This is in response to your request for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

(Insert description of requested document)

The requested record(s) will be sent at an early date. Pursuant to Departmental regulations, applicable charges will be assessed.

All communications concerning this request should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

BETTY B. DORSEY
DIRECTOR, FREEDOM OF
INFORMATION STAFF

(301) 443-1813

Enclosures:
as indicated

Exhibit 8-4

RECORDS WHICH ARE AVAILABLE TO THE PUBLIC

STAFF MANUALS AND INSTRUCTIONS (Section 20.107)

The following staff manuals and instructions which affect a member of the public are on public display in the FOI Staff Public Room. These documents may be purchased where indicated. If the documents are available from NTIS, GPO, or AOAC, the requester should be told to order it from these services.

Name of Document Available through:
Center for Drugs and Biologics Staff Manual FDA/FOIA
Center for Food Safety and Applied Nutrition Daily Operating Guide FDA/FOIA
Center for Veterinary Medicine Policy and Procedures Manual FDA/FOIA
Compliance Policy Guides Manual NTIS
Compliance Program Guidance Manual NTIS
Data Codes Manual FDA/FOIA
Drug Autoanalysis Manual FDA/FOIA
Field Management Directives FDA/FOIA
Index to Administrative Staff Manuals FDA/FOIA
Investigations Operations Manual NTIS
Inspector's Technical Guide FDA/FOIA
Investigational Training Manual FDA/FOIA
Laboratory Procedures Manual FDA/FOIA
Pesticide Analytical Manual NTIS
Regulatory Procedures Manual NTIS
Staff Manual Guides--Organization and Delegation FDA/FOIA

COMPUTER PRINTOUTS (Section 20.117, Paragraph 222 of Public Information Preamble -
December 24, 1974, Sec. 601.51)

The following printouts are available for inspection in the FOI Staff Public Room:

A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and where applicable the date the approval was withdrawn, and the date the Food and Drug Administration was notified that marketing of the products was discontinued.

A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved, showing the same information as above except that it does not show a withdrawal date.

An alphabetical list by trade name of the approved new drug applications and abbreviated new drug applications held by specific applicants.

An alphabetical list of the trade names of drugs subject to approved new drug applications and abbreviated new drug applications showing either the NDA number or the applicant or both.

An alphabetical list of generic drugs showing approved new drug applications and abbreviated new drug applications held by applicants.

PERSONNEL DATA (Section 20.110)

Name of FDA employee
Title
Grade
Position description
Salary
Work address
Work telephone number

Statistics on the prior employment experience of present FDA employees

Statistics on the subsequent employment of past FDA employees

PRODUCT CODES (Section 20.115)

Product codes for date of manufacture
Product codes for sales date

ADMINISTRATIVE ENFORCEMENT RECORDS (Section 20.101 & 20.64)

Notices of refusal of admission of an imported product
Regulatory letters and responses
Notice of Adverse Findings letters and responses
Information letters
Completed Form FD-483, List of Observations
Completed Form FD-2275, Drug Inspectional Observations

Exhibit 8-5

AFFIDAVIT

_____ (Name of Affiant), being first duly sworn, deposes and says:

1. I am the _____ (title), _____ (Office, Division, etc.), United States Food and Drug Administration.

2. In this capacity, I have custody of official records of the United States Food and Drug Administration.

3. Attached are true copies of official records of the United States Food and Drug Administration as follows:

A. (List each of the documents requested for certification e.g....) Letter dated _____ to _____ from _____.

B. Etc.

_____ (Signature)
(Name of Affiant)

(Notary statement):
County of Montgomery
State of Maryland

Subscribed and sworn to before me this ____ day of _____, 199__.

_____
(Notary Public)

My commission expires: _____

Exhibit 8-6

CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that _____ (Name of Affiant), _____ (Title of Affiant), _____ (Office, Division, etc.), United States Food and Drug Administration, whose affidavit is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provisions of Title 42, United States Code, Section 3503, and 21 C.F.R. 5.22, hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this _____ day of _____, 199___.

_____(Signature)
Name of Authorized Person in 21 C.F.R. 5.22
Title
Office

By direction of the Secretary of Health and Human Services

Exhibit 8-7

CONFIRMATION OF AMENDED ORIGINAL REQUEST

In reply refer to:

Dear _____:

This responds to your request for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act. On _____, you sent a letter in which you requested "_____(insert original request language)_____." On ___(date)___ , you verbally amended your original letter to request documentation that was releasable. We are enclosing the requested records (list them below).

(NOTE: The following "minor deletions" paragraph is optional. It always should be included whenever records are released with redaction.) In order to help reduce processing time and costs, FDA deleted certain material from the original request because a preliminary review of the records indicated that the deleted information was not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

NAME and MAIL SYMBOL OF FOIA OFFICER

Enclosures

Exhibit 8-8

PREDISCLOSURE NOTIFICATION LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In Reply Refer to:

Dear _____:

We have received a request under the Freedom of Information Act (copy enclosed) for the following record(s) submitted by your firm:

In accordance with Executive Order (E.O.) 12600 of June 23, 1987, and with the Department of Health and Human Services' regulations implementing this E.O., 45 C.F.R. 5.65(d), this letter is to provide you with an opportunity to indicate which of the enclosed record(s) or portions of record(s) you believe to be exempt under the FOIA, 5 U.S.C. 552(b)(4). Any claims of confidentiality must be adequately justified and are subject to the False Reports to the Government Act (18 U.S.C. 1001).

If you believe any of the information should be kept confidential, and if the Food and Drug Administration agrees with your views and denies disclosure of any of these records or portions thereof and the person requesting the records subsequently contests the denial in the courts, you will be required to intervene to defend the exempt status of the records (21 C.F.R. 20.53).

If I do not receive a written response from you within 5-working days after receipt of this letter, the records will be disclosed. If you assert confidentiality status for the material requested and the Food and Drug Administration determines that the material is disclosable, you will be notified and permitted five days after receipt of our decision to institute a lawsuit. Please direct your reply to (FOIA component address and the telephone number).

We are notifying the requester of these records, by copy of this letter, that we are giving you this notice and an opportunity to object.

Sincerely yours,
Component FOIA Officer
Enclosure(s):
Request Letter
Responsive records
cc: Requester
bcc: HFI-35

Exhibit 8-9

PREDISCLOSURE NOTIFICATION DISAGREEMENT LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to:

Dear _____:

This is in reply to your letter dated _____, which you submitted in response to our letter of _____ providing you an opportunity to assert the confidentiality of record(s) in accordance with Executive Order (E.O.) 12600 of June 23, 1987, and with the Department of Health and Human Services regulations implementing this E.O., 45 C.F.R. 5.65(d). We disagree with your views because _____. Therefore, we have determined that the following record(s) or portions thereof are disclosable:

In accordance with 45 C.F.R. 565(d), you will be permitted 5 days after receipt of this notification to institute suit in a United States District Court to enjoin release of the record(s) involved. If suit is not brought within that time period we will disclose the record(s).

We are notifying the requester of these records, by copy of this letter, that we are giving you this notice.

Sincerely yours,

BETTY B. DORSEY
DIRECTOR, FREEDOM OF
INFORMATION STAFF

(301) 443-1813
Enclosures:
Responsive records
cc: Requester
bcc: HFI-35

Information Disclosure Procedures, - Sharing Non-Public Information with Foreign Government Officials

PURPOSE

This subchapter sets out the procedures that should be followed when a Food and Drug Administration (FDA) Center or Office receives a request for non-public (e.g., predecisional or confidential commercial) documents from a foreign government official.

BACKGROUND

Regulations permit FDA to share certain records, on a discretionary basis, with a foreign government official who performs counterpart functions to the FDA as part of cooperative law enforcement or regulatory efforts, provided that certain conditions are met (21 C.F.R § 20.89). Records that may be shared under this provision include non-public predecisional or confidential commercial information all of which are otherwise exempt from public disclosure under the Freedom of Information Act (FOIA) or other statutory or regulatory provisions. Such disclosures are never mandatory and each request should be processed only after considering FDA's concerns for confidentiality, the requester's need for the information, and the benefit to the public health that may result. For further guidance in making this determination, see the preambles to 21 C.F.R. § 20.89 found at 58 Federal Register 61598 (November 19, 1993) and 60 Federal Register 63372 (December 8, 1995). This subchapter supplements the Center for Drug Evaluation and Research's Staff Manual Guide 4405.3 and the February 22, 1994, memorandum from Linda Horton, Director, International Policy (IP), Office of Policy, to Center Directors and the Office of Regulatory Affairs (ORA), their designated decisionmakers and contacts for 21 C.F.R. § 20.89(c), and the FDA International Working Group. That memorandum requested addressees to be responsible for identifying when it was appropriate to disclose confidential commercial information pursuant to § 20.89 and to monitor that disclosure. The following procedures are applicable in joint reviews or related information sharing on product review decisions only to the extent that these procedures facilitate such reviews. Alternative procedures that comply with applicable statutes and regulations may be developed and included in (or cross-referenced in) future edits of this subchapter. This subchapter does not address requests for publicly available information, e.g., information that is not exempt from public disclosure. Also, it does not address an instance where FDA provides an open investigatory record that does not contain confidential commercial information to a foreign government agency or international organization. In that case, FDA's transmittal letter should include a statement that the information is provided for official use only and the recipient agency should maintain the confidentiality of the material until FDA provides a written statement that the information no longer has non-public status.

RESPONDING TO REQUESTS

A foreign government official might send his/her request for non-public information directly to a Center, the Office of International Affairs, IP, ORA headquarters or district office, or other FDA headquarters office. The request should be forwarded to the contact for the receiving Center/Office, as listed in Exhibit 8-20). On February 17, 1994, David A. Kessler, M.D., designated decisionmakers to authorize release of confidential

commercial information under the regulations [21 C.F.R. §20.89(c)]. Exhibit 8-20 is an updated list of names of designated decisionmakers.

Personnel participating in compiling the response to a request for confidential commercial information, or for internal FDA memoranda on such information, should be guided by the information set out below.

1. The Center responsible for regulating the product that is the subject of the request for information generally is the "lead" Center for responding to requests. If the Center/Office that receives the request is not also the one responsible for responding, it should send a copy of the request to the appropriate Center/Office to respond. However, if the request is for publicly available information, and the receiving Center/Office has the responsive record, it may respond directly, sending a copy to the Office of International Affairs.
2. The lead Center/Office should:
   A. determine if the requested documents, in whole or in part, should be provided to the requester,
   B. prepare:
      (1) the "Conditions for the Confidential Sharing of Non-Public Information with Foreign Government Officials," and obtain the signatures for that form's attached "Certification: Foreign Government Statement of Authority and Commitment to Not Disclose" (Exhibits 8-21 and 8-22).

With the concurrence of the Office of Chief Counsel, the lead Center/Office may modify the Certification to allow for multiple requests for similar material (see Exhibit 8- 22). The lead Center/Office may, without OCC concurrence, remove item 2 in Exhibit 8-22 if it is inapplicable. For example, FDA may determine that the requester need not submit a copy of relevant statutes because: (a) FDA already has a copy (as of July 1997, FDA had "confidentiality" statutes from Canada and Australia), or (b) the request is considered routine. An example of a routine request could be one for non-public confidential commercial information from a pending or approved application where the sponsor has filed a similar application with the foreign country and has consented to release of the non-public information to the requestor.

The lead Center/Office should notify other FDA components participating in the response that the modified Certification is acceptable,

(2) unless the requester already provided the signed Sponsor's Authorization to Release Confidential Commercial and/or Trade Secret Information, a transmittal letter to the sponsor to transmit a model Sponsor's Authorization (Exhibit 8-23). The transmittal letter should clearly identify the documents for which authorization is requested. Obtain the sponsor's signature on the Authorization, and

(3) in the case of a visiting scientist, prepare and obtain the signature for the form, "Foreign Visiting Scientist Commitment to Protect Information and Assurance of No Financial Interest" (Exhibit 8-24),

C. before disclosure, prepare and obtain the appropriate FDA official's signature on whichever of the following forms is appropriate:

(1) further delegation of authority from the Commissioner's designee in 21 C.F.R. § 5.23(a)(10)(i) through (vii) to another appropriate FDA official or employee to release confidential commercial information (Exhibit 8-25),

(2) determination from the designee in 21 C.F.R. § 5.23(a)(10)(i) through (vii) to release confidential commercial information in the absence of the sponsor's consent (Exhibit 8-25). Note: Trade secret information can be disclosed only with the sponsor's written permission or to a foreign visiting scientist on FDA's premises [21 C.F.R. § 20.89(c)(1)(ii)(C)].

(3) authorization from the Deputy Commissioner for Policy, Associate Commissioner for Policy Coordination, or the Director, IP, to release non-public predecisional information (Exhibit 8-26),

D. when requested and appropriate after disclosure, prepare and obtain the appropriate FDA official's signature on the statement that the information no longer has non-public status, and the related letter to the government requester of that status (Exhibits 8-27 and 8-28),

E. if necessary, before receipt of information from a foreign government, prepare and obtain the appropriate FDA official's signature on the certification from the Commissioner's designee in 21 C.F.R. § 5.23(a)(10)(i) through (vii) (confidential commercial) or the Deputy Commissioner for Policy, Associate Commissioner for Policy Coordination, or the Director, IP, (predecisional) to protect from public disclosure non-public documents that are provided to FDA in confidence by a foreign government (see item 3.E. below) (Exhibit 8-29),

F. coordinate the compilation of responsive documents with other FDA components if necessary,

G. monitor the progress of the response; responses should be made as promptly as possible,

H. determine if the Center/Office has the name and address of the foreign government official authorized to receive the non-public documents,

I. confirm that FDA has the necessary signed regulatory forms and the transmission is appropriate, prepare the transmittal letter (Exhibit 8-30), get the letter signed, and transmit the responsive documents to the requester.

J. maintain a file for the original signed documents in items 2.B., C., D, and E., other relevant correspondence.

3. The Center/Office that originated the responsive record(s) is responsible for purging the record(s) of any information not appropriate for release under 20.89 such as patient names or trade secrets (unless the patient or the submitter of the confidential commercial information consents in writing). If you are unsure which information must be redacted, contact your FOIA officer. Information related to disclosure and examples of non-public records are set out below.

A. Confidential commercial information includes information used in one's business which is customarily held in strict confidence, such as operations, style of work, apparatus, identity, confidential statistical data, amount or source of income (e.g., a company's list of customers), profits or losses, or expenditures (of any person, firm, partnership, corporation or association). [See 21 C.F.R. § 20.61(b) and 39 Federal Register 44602, comment 78 at 44611 (December 24, 1974).] An establishment inspection report or a medical officer's review may contain confidential commercial information, or (see below) trade secret information.

B. A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process. [See 21 C.F.R. § 20.61(a)].
C. An example of a document that is considered non-public because it is part of an "open investigatory record," is the Establishment Investigation Report (EIR). The EIR may be withheld from disclosure until the administrative record is closed. The EIR record is considered closed when FDA decides that no additional administrative or regulatory action is warranted. This may be, but is not always, related to the issuance of the Warning Letter, which, when issued to the inspected firm, becomes publicly available. The Warning Letter is informal and advisory and is not a final FDA action. Therefore, the EIR record remains open until a satisfactory response to the Warning Letter is received from the firm or FDA otherwise concludes that no further administrative or regulatory action is dictated.
D. Predecisional documents include, but are not limited to, draft or proposed governmental regulations, regulatory initiatives, FDA policy or procedural statements, certain inter-governmental communications, and records of advice and recommendations between non-FDA governmental officials and FDA. The regulations also provide for a residual "catch-all" category of non-public documents to cover other types of non-public information; these are handled like predecisional documents.
E. In certain instances, FDA is able to protect from public disclosure information that the submitting foreign government indicates in writing is non-public. If requested, FDA may provide written assurances to the submitting foreign government (see item 2.E.).

EXHIBITS

EXHIBIT 8-20

CENTER/ORA DESIGNATED DECISIONMAKERS FOR DISCLOSURES UNDER 21 C.F.R. § 20.89(c):

Mark Elengold, CBER (HFM-11), Ph.: 301-827-2000, FAX: 301-594-1938
Roger Williams, M.D., CDER (HFD-2), Ph.: 301-594-5400, FAX: 301-594-6197
Joseph Levitt, CDRH (HFZ-2), Ph.: 301-443-4690 , FAX: 301-594-1320
the CDRH Contact is Fred Sadler, (HFZ-82), Ph.: 301-594-4774, FAX: 301-594-4792
Janice Oliver, CFSAN (HFS-3), Ph.: 202-205-4307, FAX: 202-205-5025 ;
the CFSAN Contact is Charles Cooper, (HFS-585), Ph.: 202-205-5042, FAX: 202-205-0165
Sharon Thompson, D.V.M., CVM, (HFV-3), Ph.: 301-594-1798, FAX: 301-594-1830
William Allaben, NCTR (HFT-30), Ph.: 501-543-7528, FAX: 501-543-7576
Marlene E. Haffner, M.D., Ph.D. (HF-35), Office of Orphan Products Development (OPD), Ph.:301-827-3666,
FAX: 301-443-4915; the OPD Contact is John McCormick, M.D. (HF-35), Ph.: 301-827-3666,
FAX: 301-443-4915
Daniel Michels, ORA (HFC-200), Ph.: 301-827-0429, FAX: 301-827-0482;
the ORA Contact is David Haggard (HFC-230), Ph.: 301-827-0393, FAX: 301-827-0482

AGENCY DECISIONMAKERS FOR DISCLOSURES UNDER 21 C.F.R. § 20.89(d):

William B. Schultz, Deputy Commissioner for Policy (HF-22), Ph.: 301-827-3370, FAX: 301-443-5930
William K. Hubbard, Associate Commissioner for Policy Coordination (HF-11), Ph.: 301-827-3360, FAX: 301- 594-6777
Linda R. Horton, Director, International Policy, Office of Policy (HF-23), Ph.: 301-827-3344, FAX: 301-443-6906

EXHIBIT 8-21

UNITED STATES FOOD AND DRUG ADMINISTRATION
Conditions for the Confidential Sharing of Non-Public Information with Foreign Government Officials

The United States Food and Drug Administration (FDA), an Agency within the United States Department of Health and Human Services, is charged with protecting and promoting the health of the American people. It is responsible for assuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.

In an effort to enhance regulatory and enforcement cooperation between FDA and foreign government officials who perform counterpart functions to FDA, FDA has promulgated a regulation, 21 C.F.R. § 20.89 governing the communication of non-public information with foreign government officials (see attached). 21 C.F.R. § 20.89 permits FDA, on a discretionary basis, to exchange with foreign government officials non-public predecisional or confidential commercial information concerning FDA regulated products. Such an exchange between FDA and a foreign government will not compel FDA, if requested, to disclose the information to the public.

Before FDA may share non-public predecisional or confidential commercial information with foreign government officials, FDA must receive a written statement from the foreign agency that: (1) establishes the agency's authority to protect the information from public disclosure, and (2) commits the agency not to disclose such information without written confirmation from FDA that the information no longer has non-public status, or, in most cases involving confidential commercial information concerning a regulated product, without the consent of the sponsor of the information. A copy of this commitment form for execution by appropriate foreign government officials is attached to this letter.

Once FDA receives the written statement setting out the commitment on the part of the foreign agency, FDA may share the information only if it makes the following findings: (1) in the case of the exchange of non-public predecisional information, the exchange must be reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, (2) in the case of confidential commercial information, FDA must find either that the sponsor for the product application has provided written authorization for the exchange, or that disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation. In the case of the exchange of a much narrower class of information relating primarily to the production process, namely, trade secrets, FDA will disclose the information only if the submitter of the information provides written authorization to FDA.

As a regulatory and law enforcement Agency, it is important that FDA not provide any company with a competitive advantage or place a submitting company at a disadvantage relative to its competitors through unauthorized disclosure of proprietary information. It is essential for the maintenance of cooperative relations that foreign officials engaged in information exchanges with FDA understand and respect the obligations to protect non-public information from unauthorized disclosure. In fact, such unauthorized disclosure

could subject persons to criminal or other sanctions. For that reason it is essential that adequate security measures be taken to prevent the unauthorized release of exchanged information.
The attachment is the certification that FDA needs prior to releasing the information to your government. Please have the appropriate government official sign and return the form to FDA (contact and address).
Attachment: Certification

EXHIBIT 8-22

CERTIFICATION: FOREIGN GOVERNMENT STATEMENT OF AUTHORITY AND COMMITMENT TO NOT DISCLOSE INFORMATION PROVIDED BY THE FOOD AND DRUG ADMINISTRATION (FDA)

Reference: (Application number or other identifier) Approved on:_____
(Specific description including dates and submission/volume/page numbers)
(Product trade name)

The _____, a governmental agency ("agency") of the country of, _____, which is entrusted with protecting the public's health, is requesting that FDA provide the information referenced above concerning safety, effectiveness, or quality. The request is for the limited purpose of conducting cooperative law enforcement or regulatory efforts. My agency understands that some or all of the information in these documents is considered to be non-public predecisional or confidential commercial information which is exempt from disclosure to the public within the United States. FDA considers maintaining the confidential nature of these materials to be extremely important. My agency further understands that disclosure by the recipient government of the information contained in these documents could be a criminal violation of federal law and could seriously jeopardize any further cooperative interactions between FDA and the recipient government counterpart organization.

Therefore, _____ (agency) certifies that it:

1. has the authority to protect the non-public predecisional or confidential commercial information from public disclosure,

2. has attached copies of the relevant statutes, regulations, court decisions, or other documents that establish this authority,

3. will not disclose the information without the written permission of the submitter of this information or a written statement from FDA that the information no longer has non-public status, and

4. if different from the undersigned, has designated _____ (printed name, title) to receive the non-public information at _____ (address, telephone, facsimile).

_____ _____

Signature Date
of foreign government official
Print or type the following:
Name of government official:

_____

Title of government official:

_____

Name of agency:

_____

Address:

_____

_____

Telephone and facsimile:

_____

AN ADDITIONAL SIGNATURE IS REQUIRED IF THE FOREIGN GOVERNMENT OFFICIAL IS AN AGENT CONTRACTED BY THE FOREIGN GOVERNMENT OR AN EMPLOYEE OF AN INTERNATIONAL ORGANIZATION HAVING RESPONSIBILITY TO FACILITATE GLOBAL HARMONIZATION [SEE 21 C.F.R. §20.89(d)(3)].

_____ _____

Signature Date
of foreign government official
Print or type the following:
Name of government official:

_____

Title of government official:

_____

Name of agency:

_____

Address:

_____

_____

Telephone and facsimile:

_____

EXHIBIT 8-23

MODEL SPONSOR'S AUTHORIZATION TO RELEASE CONFIDENTIAL COMMERCIAL AND/OR TRADE SECRET INFORMATION TO A FOREIGN GOVERNMENT AGENCY

(SPONSOR SHOULD PREPARE ON ITS LETTERHEAD)

Freedom of Information Staff
Attention: _____(Name and Title)
Center for (Address)

RE: (Name of Regulated Product, Including Active Ingredient for a Drug Product)
(Application Number) (Date of Approval)

Dear :

On behalf of _____ , the sponsor of the above-referenced regulated product, I hereby consent to disclosure of the following documents by the United States Food and Drug Administration (FDA) to the (name of requesting foreign agency) solely for the purpose of _____. I understand that the documents may contain confidential commercial or financial information, within the meaning of 18 U.S.C. 1905, 21 U.S.C. 331(j), and U.S.C. 552(b)(4) or other information that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosing the documents to (name of requester).

Documents to be disclosed: (list them or describe them accurately):

Consent is given to the documents being sent without deletion of confidential commercial or trade secret information.

As indicated by my signature, I am the authorizing official for the sponsor and my full name, title, address, telephone number, and facsimile number are set out below for verification. A copy of this letter is being sent to the foreign agency requesting the information.

Sincerely, (Signature)
(Printed name)
(Title)
(Telephone Number)
(Facsimile Number)
cc: Name of foreign government agency

EXHIBIT 8-24

FOREIGN VISITING SCIENTIST
COMMITMENT TO PROTECT INFORMATION
AND ASSURANCE OF NO FINANCIAL INTEREST

Whereas, I, _____, am to participate on a special assignment with the United States Food and Drug Administration ("FDA"), I hereby agree, subject to the penalties of Section 1905, Title 18 U.S.C., Crimes and Criminal Procedures (18 U.S.C. 1905), the Economic Espionage Act (18 U.S.C. 1831-39), and Section 301(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(j)], cited below, as well as other applicable statutory and regulatory provisions to protect all non-public information entrusted to me in the following manner:

1. to store the non-public information in the secured offices of the FDA. and
2. to grant access to the non-public information only to known employees of the FDA or to such other persons as may be designated in writing by the FDA.

Further, I agree to:

1. assist in reviewing the security measures I will employ in protecting non-public information entrusted to me,
2. return all non-public information and notes pertinent thereto to the FDA upon completion of my assignment, or upon the FDA's request,
3. report in writing to the FDA official I am assigned to, all incidents in which unauthorized persons might have gained access to non-public information entrusted to me, and
4. not release, publish, or disclose such non-public information specifically any of the facts involved in this matter, including any trade secret matter.

I understand the provisions of 21 U.S.C. 331(j) and 18 U.S.C. 1831-29 and 1905 and that I may be subject to criminal penalties prescribed by law for any violations thereof.

NO FINANCIAL INTEREST

I hereby swear that I do not currently have any financial interest whatsoever in any aspect of industry related to a product regulated by the FDA, nor am I planning to enter into that field within one year after concluding my duties with the United States FDA.

SIGNATURE DATE

TYPED OR PRINTED NAME OF VISITOR
WITNESSED (SIGNATURE) DATE
TYPES OR PRINTED NAME OF WITNESS

EXHIBIT 8-25

INTERNAL MEMORANDUM REQUESTING FURTHER DELEGATION OF AUTHORITY AND/OR DETERMINATION TO DISCLOSE CONFIDENTIAL COMMERCIAL INFORMATION TO FOREIGN GOVERNMENT

(DATE)

FROM: (Insert Name of Person Requesting the Further Delegation or Determination)

SUBJECT: Further Delegation of Authority and/or Determination to Disclose Confidential Commercial Information to Foreign Government

TO: Designee in 21 C.F.R. § 5.23 (a)(10)(i) through (vii)

On _____ (date) (name of foreign government agency) requested the following confidential commercial information:

In accordance with 21 C.F.R. §5.23 and § 20.89, the purpose of this memorandum is to request your authorization regarding the items checked below.

_____1. Delegation of Authority.

Delegation of authority from you to (name of person in Center/Office) or his or her designee to release confidential commercial information described above after FDA receives written authorization for the release from the sponsor.

_____2. Determination Regarding Release of Certain Confidential Commercial Information.

In accordance with 21 C.F.R. §5.23 and § 20.89, this memorandum requests your authorization to release the confidential commercial information described above to _____. The information is normally released only after FDA receives written authorization for the release from the sponsor of the confidential commercial information.

In rare situations, such as where the sponsor has refused to consent to the release of the confidential commercial information or where consent is impractical (for example, consent from the sponsor would be impractical where the confidential commercial information might be relevant in pending regulatory actions against the sponsor), FDA may disclose confidential commercial information to a foreign government if FDA determines that disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning a product's safety, efficacy, or quality or information concerning an investigation.

In this instance, the sponsor has (check one):
_____ consented to the release of the confidential commercial information described above (the sponsor's written consent is attached)
_____ refused to consent to the release of the confidential commercial information described above; or
_____ has not been asked to consent to the release of the confidential commercial information described above. Consent was not sought because
_____

Consequently, we request that you determine whether disclosure of the confidential commercial information may occur, without the sponsor's consent, on the grounds that disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product, or information concerning an investigation.

(Signature)

PLEASE INDICATE CONCURRENCE OR NON-CONCURRENCE BY CHECKING THE APPROPRIATE ITEMS:

1. I AGREE _____, DO NOT AGREE _____ TO DELEGATE AUTHORITY TO _____ (NAME) TO RELEASE CONFIDENTIAL COMMERCIAL INFORMATION AFTER THE SPONSOR PROVIDES WRITTEN AUTHORIZATION FOR SUCH RELEASE.

_____
_____
[Signature of Designee in 21 C.F.R. § 5.23(a)(10)(i) through (vii)]
Date
Title of Designee

2. I DO _____, DO NOT _____ DETERMINE THAT PUBLIC HEALTH REASONS EXIST THAT WARRANT DISCLOSURE OF THE CONFIDENTIAL COMMERCIAL INFORMATION IN THE ABSENCE OF SPONSOR AUTHORIZATION.

_____
_____
[Signature of Designee in 21 C.F.R. §5.23(a)(10)(i) through (vii)]
Date
Title of Designee
cc: Designee

EXHIBIT 8-26

INTERNAL MEMORANDUM REQUESTING DETERMINATION TO DISCLOSE NON-PUBLIC PREDECISIONAL INFORMATION TO FOREIGN GOVERNMENT

(DATE)

FROM: (Insert Name of Person Requesting the Further Delegation or Determination)

SUBJECT: Authorization to Disclose Non-Public Predecisional Information to Foreign Government

TO: (Insert One Title) The Deputy Commissioner for Policy, the Associate Commissioner for Policy Coordination, or the Director, International Policy, Office of Policy

On _____ (date)
_____ (name of foreign government agency) requested the following non-public predecisional information:

_____
_____
_____
_____
_____
_____.

In accordance with 21 C.F.R. § 20.89(d)(1), the purpose of this memorandum is to request your authorization release this information for the following reasons:

_____
_____
_____
_____
_____
_____
_____

(Signature)

CONCURRENCE/NON-CONCURRENCE:

I DO _____, DO NOT _____ AUTHORIZE DISCLOSURE OF THE PREDECISIONAL INFORMATION DESCRIBED ABOVE.

(Insert title of addressee)
Date
cc: W. Schultz HF-22, W. Hubbard HF-11, L. Horton HF-23

EXHIBIT 8-27

STATEMENT (MEMORANDUM TO THE RECORD) THAT
REQUESTED INFORMATION NO LONGER HAS NON-PUBLIC STATUS

(DATE)

FROM: (Name of Appropriate Designee)

On _____ (date) FDA sent non-public records to _____ (name of foreign government agency). The non-public records are described below:_____
_____
_____
_____
_____

Pursuant to 21 C.F.R. § 20.89 and the commitment it provided, on _____, the foreign agency sent a written request for a determination that the records no longer have non-public status so it can disclose the information.

THE RECORDS DO _____ DO NOT _____ HAVE PUBLIC STATUS FOR THE FOLLOWING
REASONS:_____
_____
_____
_____
_____

(Signature)

EXHIBIT 8-28

MODEL LETTER NOTIFYING REQUESTER THAT THE RECORDS NO LONGER HAVE NON-PUBLIC STATUS

FOR OFFICIAL USE ONLY

(Date)

(Name and address of requester)

Dear _____:

On _____, the Food and Drug Administration (FDA) sent _____ (name of requesting foreign agency) non-public records. This letter responds to your _____(date) request for a determination that the records described below no longer have non-public status.

(Insert title of non-public document)

FDA has determined that the non-public records (select one) continue to have non-public status and should not be disclosed to the public according to the terms of the "Certification: Foreign Government Statement of Authority and Commitment to Not Disclose" that your agency signed on _____, and 21 C.F.R. § 20.89, OR no longer have non-public status.

If you have any questions, please contact me at (insert address, phone number, or electronic mail address).

Sincerely,

(Name of Appropriate FDA Designee)

cc: Name of sponsor, if applicable
bcc: Name of any participating FDA component

EXHIBIT 8-29

FOOD AND DRUG ADMINISTRATION CONFIDENTIALITY AGREEMENT
TO PROTECT NON-PUBLIC PREDECISIONAL OR CONFIDENTIAL
COMMERCIAL INFORMATION
SUBMITTED TO FDA BY A FOREIGN GOVERNMENT

I certify that:

(1) The Food and Drug Administration (FDA) has authority to protect from public disclosure, pursuant to 21 C.F.R. § 20.89, any non-public predecisional or confidential commercial information that are provided to me by the (name of submitting foreign government agency).
(2) I have attached copies of relevant statutes, regulations, court-decisions, or other relevant documents regarding this authority.
(3) FDA will not disclose non-public predecisional or confidential commercial document received from and for which (name of submitting foreign government agency) has clearly stated that it is provided in confidence without the written confirmation from (name of foreign government agency) that the document no longer has non-public status.
(4) If necessary, FDA will complete any supplementary document that is needed to enable (foreign government agency) to disclose confidential commercial information to an FDA scientist visiting that agency.

Date
Signature
(Any official designated by the Commissioner, for Confidential Commercial Information)
(Deputy Commissioner for Policy, Associate Commissioner for Policy Coordination, or Director, International Policy, for Non-Public, Predecisional or Other Document)

Name of FDA government official:

_____

Title of FDA government official:

_____

Agency name and address:
Food and Drug Administration
5600 Fishers Lane (Mailing Symbol)
Rockville, MD 20857
Telephone and facsimile: _____

EXHIBIT 8-30

MODEL LETTER TRANSMITTING NON-PUBLIC PREDECISIONAL OR CONFIDENTIAL COMMERCIAL INFORMATION

FOR OFFICIAL USE ONLY

(Date)

(Name and address of requester)

Dear _____:

This letter responds to the _____ (name of requesting agency) request dated _____ for information from the Food and Drug Administration (FDA). I am enclosing the following document(s), which contain non-public predecisional or confidential commercial information.

(Insert title of non-public document)

This non-public information is provided for official use only and should be used according to the terms of the "Certification: Foreign Government Statement of Authority and Commitment to Not Disclose" that your agency signed on _____, and 21 C.F.R. § 20.89, which provided that the requesting agency maintain the confidentiality of this material until either the sponsor provides you with written permission to disclose or the FDA provides a written statement that the information no longer has non-public status.

If you have any questions, please contact me at (insert address, phone number, or electronic mail address).

Sincerely,

(Name of Appropriate FDA Designee)

cc: Name of sponsor, if applicable
bcc: Name of any participating FDA component

Information Disclosure, - Sharing Non-Public Information with Federal Government Officials

PURPOSE
This subchapter describes the procedures for handling requests from other federal government departments or agencies for non-public information to the Food and Drug Administration (FDA).

AUTHORITY
1. 21 U.S.C. ' 331(j) (Federal Food, Drug, and Cosmetic Act)
2. 5 U.S.C. ' 552, as amended by Public Law 99-750, Sec. 1801-1804, and the "Electronic Freedom of Information Amendments of 1996" (H.R. 3802)
3. 18 U.S.C. ' 1905 (Trade Secrets Act)
4. 21 C.F.R. Part 20
5. 21 C.F.R. ' 5.23
6. December 2, 1996, Memorandum from Associate Commissioner for Regulatory Affairs to the Deputy Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA), the Director and Deputy Director, Office of Enforcement (OE), ORA, and the Director, Division of Compliance Policy (DCP), OE, ORA.

GENERAL
FDA's practice regarding requests for non-public information from other federal government departments and agencies is governed by 21 C.F.R. " 5.23(a) and 20.85. Section 20.85, ADisclosure to other Federal government departments and agencies,@ states that FDA records otherwise exempt from public disclosure may be disclosed to other federal government departments and agencies pursuant to certain procedures. These procedures are to be used for oral as well as documentary disclosures of non-public information.
Generally, such a request is not handled through the normal Freedom of Information Act (FOIA) process. The federal government requester must provide written assurances to FDA that it will not further disclose the information, and FDA must specifically authorize the release. (21 C.F.R. ' 20.85). Additional information is set out below.

1. The fact that FDA shares the records with another federal agency under these conditions does not waive FDA=s ability to assert any applicable FOIA exemptions if a subsequent FOIA request is made for the same records. The prohibition on further disclosures is intended to preserve FDA=s ability to oppose, where appropriate, any subsequent request for the records made either to FDA or to the other federal agency. These procedures ensure that no public disclosure is taking place when FDA shares the records with the other agency so that no obligation arises to disclose the records to any other requester. (21 C.F.R. " 20.21 and 20.81).
2. Except as provided in paragraph 3 below, any non-public information that would be protected under FOIA may be shared with a federal government agency. Nevertheless, FDA must consider whether the disclosure is warranted in each specific case. Examples of non-public information that FDA might share include deliberative process information [5 U.S.C. ' 552(b)(5); 21 C.F.R. ' 20.62], or records compiled for

law enforcement purposes [5. U.S.C. ' 552(b)(7)(A); 21 C.F.R. ' 20.101]. Other examples are described in items 3 and 5 below.

3. Section 301(j) of the Federal Food, Drug, and Cosmetic Act ("Act") prohibits the "revealing, other than to the Secretary or officers or employees of the Department,...any information...concerning any method or process which as a trade secret is entitled to protection" [21 U.S.C. ' 331(j)]. Therefore, FDA may not share trade secret information with federal government agencies outside the Department of Health and Human Services (DHHS) unless the submitter of the trade secret consents in writing. Similarly, the Trade Secrets Act prohibits a federal employee from disclosing, in any manner or to any extent not authorized by law, any trade secrets or confidential commercial information (18 U.S.C. ' 1905). See also 21 C.F.R. ' 20.61. FDA may share confidential commercial information under 21 C.F.R. ' 20.85 with a federal government agency because such disclosure is not considered a public disclosure.

4. The Privacy Act prohibits an agency from disclosing information that is contained in a system of records concerning an individual to any person (or to another agency) without the prior written consent of the individual to whom the record pertains [5 U.S.C. ' 552(a)]. See this subchapter, "Freedom of Information Act," for more detail about the Privacy Act. Not all FDA records that contain personal privacy information are contained in a Privacy Act system of records and are thereby subject to the Privacy Act. If a record is protected by the Privacy Act, FDA may disclose the record pursuant to one of twelve exceptions to the rule of no disclosure without consent." One of the exceptions is to "...another agency...under the control of the United States for a civil or criminal law enforcement activity...if the head of the agency...has made a written request..." [5 U.S.C. ' 552(b)(7)]. Nevertheless, FDA must carefully consider whether personal information is appropriate for exchange under one of these exemptions.

5. Information, the disclosure of which would constitute either a "clearly unwarranted" [5 U.S.C. ' 552(b)(6)] or an "unwarranted" [5 U.S.C. ' 552(b)(7)(C)] invasion of personal privacy, that is not part of a Privacy Act system of records, is exempt from disclosure under FOIA (see 21 C.F.R. ' 20.63). The extent to which FDA will share this non-public information with a federal government agency or Congress should be determined, in consultation with the Division of Compliance Policy (DCP), Office of Enforcement (OE), Office of Regulatory Affairs (ORA), on a case-by-case basis.

LIMITATIONS OF GUIDANCE

This subchapter does not cover the following:

1. State and Local Government Officials: Refer to 21 C.F.R. ' 20.88, ACommunications with State and local government officials,@ and Chapter 8 in this Regulatory Procedures Manual.
2. Congress: Employees who receive requests from Congressional staffers should contact the FDA=s Office of Legislative Affairs (OLA).
3. General Accounting Office (GAO): Employees who receive requests from GAO should refer them to the FDA Liaison Officer with the GAO in OLA.

4. Office of Technology Assessment (OTA): Employees who receive requests from the OTA should refer them to the FDA Liaison Officer with the OTA in OLA.
5. Disclosures to other federal agencies that are within the DHHS. In such cases, please contact DCP for additional guidance.
6. Disclosures of publicly releasable documents.

RESPONSIBILITIES

Disclosure of non-public records and information to other federal agencies must be authorized by the Associate Commissioner of Regulatory Affairs, pursuant to 21 C.F.R. " 20.85 and 5.23. The Associate Commissioner for Regulatory Affairs, in a December 2, 1996 memorandum, pursuant to 21 C.F.R. " 5.20(b), and 5.23(a)(1), has designated the Director and Deputy Director, OE, and the Director, DCP, OE, the authority to make determinations to disclose official records and information under 21 C.F.R. ' 20.85.
The organizational unit of FDA making the disclosure of non-public information held by FDA must be authorized to do so, whether the information is part of a cooperative law enforcement effort, or provided at the request of the other agency for its own investigation. An employee of the FDA may only discuss information otherwise exempt from public disclosure with another federal agency when authorized. (Depositions will be authorized separately as testimony requests under 21 C.F.R.' 20.1.) Employees who will be interviewed may wish to consult with a FOIA Officer if they are uncertain about the scope of information prohibited from disclosure by 21 U.S.C. ' 331(j).
DCP is responsible for staff work regarding requests for non-public information from other federal government departments and agencies.
This subchapter does not address disclosure of publicly releasable documents.
Other headquarters and district office components are responsible for assisting DCP in responding to requests regarding non-public information originated by those components.
The Office of Chief Counsel (OCC) is responsible for providing guidance and assistance in legal aspects of handling these requests.

PROCEDURES

An FDA employee who receives a verbal or written request for non-public information from another federal agency may wish to inform the component's FOIA Officer, and should either refer the requester to DCP or advise the requester to follow the procedure set out below.

1. Submit a written request (on the requester's letterhead) for non-public information to:

   Director, Division of Compliance Policy
   Office of Regulatory Affairs (HFC-230)
   Food and Drug Administration
   5600 Fishers Lane
   Rockville, Maryland 20857
   (Attention: David Haggard or Eileen Rhoads) Facsimile number: 301-827-0482

2. Include information in the request (see Exhibit 8-10) about:
   A. the type of records/information requested, including the firm and/or product name(s),

B. whether the request for information is the result of an ongoing investigation, and

C. the purpose for which the information is requested.

Generally, there is no blanket authorization upon which another requesting federal agency may rely to obtain additional information, unless the request for information is part of an ongoing investigation for which the federal agency submitted a prior request. This is handled on a case-by-case basis.

3. Include a written statement that the requester will protect the confidentiality of the non-public records and not further disclose the information without the written permission of FDA or, in the case of confidential commercial information, the permission of the submitter (21 C.F.R. ' 20.85). (See Exhibit 8-10)

Upon receipt of the request and the written assurance, DCP should:

1. consult with the appropriate FDA component that has the responsive documents and/or OCC, if necessary to determine the propriety of releasing the information,

2. if the request is for non-public information originally obtained from a federal government agency other than FDA, determine the appropriate contact person in that agency and, on a case-by-case basis, either forward the request to the other federal government agency or return the request to the requester to forward to that agency. If FDA forwards the request to the other federal government agency, it will notify the requester of that action and monitor the response. It will be the requester's responsibility to satisfy any additional requirements for confidentiality that the other federal government agency requires. The response will be made by the other agency,

3. prepare a memorandum of authorization to disclose to be signed by the Associate Commissioner for Regulatory Affairs or designee,

4. inform the requester of the status of the authorization, by sending a copy of the written authorization or denial of authorization to the requester,

5. send a copy of the signed authorization to the participating headquarters or district office, and

6. maintain a file of the original request and the signed authorization or denial of authorization to disclose.

Upon receipt of the signed authorization to disclose non-public information, the headquarters or district office with the responsive documents should:

1. determine if the records or information contain confidential commercial, trade secret, or other non-public information, consulting with the component's FOIA Officer if needed, making sure that no trade secret information is disclosed without the submitter's consent, and

2. prepare a transmitting letter (see Exhibit 8-11) that contains a statement that the enclosed documents may contain non-public information and must not be disclosed without further authorization.

EXHIBITS

8-10 Model Letter Requesting Non-Public Information

8-11 Model Letter Transmitting Non-Public Predecisional or Confidential Commercial Information

EXHIBIT 8-10

MODEL LETTER REQUESTING NON-PUBLIC INFORMATION
(ON THE REQUESTER'S LETTERHEAD)

Director, Office of Enforcement, Office of Regulatory Affairs
c/o Director, Division of Compliance Policy (HFC-230)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Attention: Mr. David Haggard

Dear Mr. Haggard:

The _____ (title of federal government agency) would like the following non-public information pursuant to 21 C.F.R. 20.85 (list the type of records/information requested, including the firm and/or product name(s))
_____.

The purpose for which the information is requested is
_____.
The records will only be used for the following authorized law enforcement activity: _____. (Also, indicate whether the request for information is the result of an ongoing investigation, and if it is, give the details.)

I certify that the law enforcement activity is authorized by law, that the records or information will be used only for the stated purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

I understand that 21 U.S.C. 331(j) of the Federal Food, Drug, and Cosmetic Act prohibits disclosure of trade secret information outside the Department of Health and Human Services.

If you have any questions, please contact me at: (indicate address, telephone number and facsimile number).

Sincerely,

Name and Title of Requester

EXHIBIT 8-11

MODEL LETTER TRANSMITTING NON-PUBLIC PREDECISIONAL OR CONFIDENTIAL COMMERCIAL INFORMATION

FOR OFFICIAL USE ONLY

(Date)

(Name and address of federal government agency requester)

Dear _____:

This letter responds to your _____ (date) request for information from the Food and Drug Administration (FDA). I am enclosing the following document(s), which contain non-public (insert one: confidential commercial, trade secret, privacy, etc.) information.

(Insert title of non-public document)

This non-public information is provided for official use only and should be used according to the written assurance to protect the confidentiality of the information that your agency provided on _____, and 21 C.F.R. 20.85, which requires that the requesting federal government agency maintain the confidentiality of this material until FDA provides written permission for disclosure of the non-public information.

If you have any questions, please contact me at (insert address, phone number, or electronic mail address).

Sincerely,

David Haggard (or Name of Appropriate FDA Designee)

cc: Name of any participating FDA component

Information Disclosure, Sharing Non-Public Information with State and Local Government Officials

PURPOSE

This chapter sets out the procedures that should be followed when a Food and Drug Administration (FDA) Center or Office receives a request for non-public (e.g., predecisional or confidential commercial) documents from a state or local government official who is not commissioned by FDA.

BACKGROUND

Regulations permit FDA to share certain records, on a discretionary basis, with state or local government officials who perform counterpart functions to FDA as part of cooperative law enforcement or regulatory efforts, provided that certain conditions are met (21 C.F.R 20.88). Records that may be shared under this provision include non-public predecisional or confidential commercial information all of which are otherwise exempt from public disclosure under the Freedom of Information Act (FOIA) or other statutory or regulatory provisions. Such disclosures are never mandatory and each request should be processed only after considering FDA's concerns for confidentiality, the requester's need for the information, and the benefit to the public health that may result. For further guidance in making this determination, see the preambles to 21 C.F.R. 20.88 found at 58 Federal Register 61598 (November 19, 1993) and 60 Federal Register 63372 (December 8, 1995). This chapter does not address: (1) communications with state or local officials who are commissioned pursuant to 21 U.S.C. 372(a) (see RPM Chapter 3); (2) responsibilities related to regulatory requirements when a state scientist visits FDA; (3) requests for publicly available information, e.g., information that is not exempt from public disclosure; or (4) an instance where FDA provides an open investigatory record that does not contain confidential commercial information. In the last item, FDA's transmittal letter should include a statement that the information is provided for official use only and the recipient agency should maintain the confidentiality of the material until FDA provides a written statement that the information no longer has non-public status.

RESPONDING TO REQUESTS

A state or local government official might send his/her request for non-public information directly to a Center, Office of Regulatory Affairs (ORA) headquarters or district office, or other FDA headquarters office. Personnel participating in the response for confidential commercial information, or for internal FDA memoranda on such information, should be guided by the information set out below.

1. The receiving Center/Office should send a copy of the request to ORA's Division of Federal-State Relations ("HFC-150") (ORA will determine the appropriate Center/Office to respond) unless the request is for publicly available information. In that case, the Center/Office should not send a copy of the request to HFC-150 and may either respond directly or coordinate the response with the appropriate Center/Office.
2. HFC-150 should:
   A. determine which Center/Office is appropriate to respond to the request for non-public information and advise that component (HFC-150 might determine that the receiving Center/Office also should be the responding one),
   B. give the responding Center/Office the name and address of the state or local government official authorized to receive the non-public documents, which may include an FDA-commissioned official (see RPM, Chapter 3),
   C. prepare the "Conditions for the Confidential Sharing of Non-Public Information with State and Local Government Officials," and obtain the signatures for that form's attached "Certification: State and Local Government Statement of Authority and Commitment to Not Disclose" (Exhibits 8-12 and 8-13),
   D. before disclosure, prepare and obtain the appropriate FDA official's signature on whichever of the following forms is appropriate:
      (1) further delegation of authority from the Commissioner's designee in 21 C.F.R. 5.23(a)(10)(i) through (vii) to another appropriate FDA official or employee to release confidential commercial information (Exhibit 8-14),
      (2) determination from the designee in 21 C.F.R. 5.23(a)(10)(i) through (vii) to release confidential commercial information in the absence of the sponsor's consent (Exhibit 8-14). Note: Trade secret information can be disclosed only with the sponsor's written permission or to a state visiting scientist on FDA's premises [21 C.F.R. 20.88(d)(1)(ii)(C)],
      (3) authorization from the Deputy Commissioner for Policy, Associate Commissioner for Policy Coordination, or the Director, International Policy, Office of Policy, to release non-public predecisional information (Exhibit 8-15),
   E. when requested and appropriate after disclosure, prepare and obtain the appropriate FDA official's signature on the statement that the information no longer has non-public status, and the related letter to the government requester of that status (Exhibits 8-16 and 8-17),
   F. maintain a file for the original signed documents in items 2 C., D., and E., other relevant correspondence sent to HFC-150 by the Center/Office, and the list of requester officials authorized to receive the responsive documents.
3. The responding Center/Office should:
   A. determine if the requested documents, in whole or in part, should be provided to the requester,
   B. unless the requester already provided the signed Sponsor's Authorization to Release and the Center/Office sent it to HFC-150, prepare a transmittal letter to the sponsor to transmit a model Sponsor's Authorization to Release Confidential Commercial and/or Trade Secret Information (Exhibit 8-18). The transmittal letter

should clearly identify the documents for which authorization is requested. Obtain the sponsor's signature on the Authorization,

C. monitor the progress of the response; responses should be made as promptly as possible, and

D. confirm that FDA has the necessary signed regulatory forms and the transmission is appropriate, prepare the transmittal letter (Exhibit 8-19), get the letter signed, and either:

(1) transmit the responsive documents to the requester after notifying HFC-150, or

(2) forward the responsive documents to HFC-150 to transmit. And,

4. The Center/Office that originated the responsive record(s) is responsible for purging the record(s) of any information not appropriate for release under 20.88 such as patient names or trade secrets (unless the submitter consents in writing). If you are unsure about whether information must be redacted, contact your FOIA officer.

EXHIBITS

8-12 Conditions for the Confidential Sharing of Non-Public Information with State and Local Government Officials

8-13 Certification: State and Local Government Statement of Authority and Commitment to Not Disclose Information Provided by FDA

8-14 Internal Memorandum Requesting Further Delegation of Authority and/or Determination to Disclose Confidential Commercial Information to State or Local Government

8-15 Internal Memorandum Requesting Determination to Disclose Non-Public Predecisional Information to State or Local Government

8-16 Statement That Requested Information No Longer Has Non-Public Status 8-17 Model Letter Notifying Requester That The Records No Longer Have Non-Public Status

8-18 Model Sponsor's Authorization to Release Confidential Commercial and/or Trade Secret Information to a State/Local Government Agency

8-19 Model Letter Transmitting Non-Public Predecisional or Confidential Commercial Information

EXHIBIT 8-12

UNITED STATES FOOD AND DRUG ADMINISTRATION

Conditions for the Confidential Sharing of Non-Public Information with State and Local Government Officials

The United States Food and Drug Administration (FDA), an Agency within the United States Department of Health and Human Services, is charged with protecting and promoting the health of the American people. It is responsible for assuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.

In an effort to enhance regulatory and enforcement cooperation between FDA and state and local government officials who perform counterpart functions to FDA, FDA promulgated a regulation, 21 C.F.R. 20.88 governing the communication of non-public information with state and local government officials (see attached). 21 C.F.R. 20.88 permits FDA, on a discretionary basis, to exchange with state and local officials non-public predecisional or confidential commercial information concerning FDA regulated products. Such an exchange between FDA and a state or local government will not compel FDA, if requested, to disclose the information to the public.

Prior to the amendment, 21 C.F.R. 20.88 only addressed the exchange of non-public information with state and local officials who were commissioned by FDA and the exchange, with non-commissioned officials, of information that was non-public solely by reason of its being contained in an investigatory record compiled for law enforcement purposes. The amendment does not affect either of these provisions. Rather, it increases the kinds of information that FDA is able to exchange with non-commissioned officials. Before FDA may share non-public predecisional or confidential commercial information with non-commissioned state or local officials, FDA must receive a written statement from the state or local agency that: (1) establishes the agency's authority to protect the information from public disclosure, and (2) commits the agency not to disclose such information without written confirmation from FDA that the information no longer has non-public status, or, in most cases involving confidential commercial information concerning a regulated product, without the consent of the sponsor of the information. A copy of this commitment form for execution by appropriate state or local government officials is attached to this letter.

Once FDA receives the written statement setting out the commitment on the part of the state or local agency, FDA may share the information only if it makes the following findings: (1) in the case of the exchange of non-public predecisional information, the exchange must be reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements, (2) in the case of confidential commercial information, FDA must find either that the sponsor for the product application has provided written authorization for the exchange, or that disclosure would be in the interest of public health by reason of the state government s possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the state government being able to exercise its regulatory authority more expeditiously than FDA. In the case of the exchange of a much narrower class of information relating primarily to the production

process, namely, trade secrets, FDA will disclose the information only if the submitter of the information provides written authorization to FDA.

As a regulatory and law enforcement Agency, it is important that FDA not provide any company with a competitive advantage or place a submitting company at a disadvantage relative to its competitors through unauthorized disclosure of proprietary information. It is essential for the maintenance of cooperative relations that state and local officials engaged in information exchanges with FDA understand and respect the obligations to protect non-public information from unauthorized disclosure. In fact, such unauthorized disclosure could subject persons to criminal or other sanctions. For that reason it is essential that adequate security measures be taken to prevent the unauthorized release of exchanged information.

The attachment is the certification that FDA needs prior to releasing the information to your government. Please have the appropriate government official sign and return the form to FDA (contact and address).

Attachment: Certification

EXHIBIT 8-13

CERTIFICATION: STATE AND LOCAL GOVERNMENT STATEMENT OF AUTHORITY
AND COMMITMENT TO NOT DISCLOSE INFORMATION PROVIDED BY THE FOOD AND DRUG ADMINISTRATION (FDA)

Reference: (Application number or other identifier) Approved on:_____
(Specific description including dates and submission/volume/page numbers)
(Product trade name)

The _____, a governmental agency ("agency") of the state of _____, which is entrusted with protecting the public's health, is requesting that FDA provide the information referenced above concerning safety, effectiveness, or quality. The request is for the limited purpose of conducting cooperative law enforcement or regulatory efforts.
My agency understands that some or all of the information in these documents is considered to be non-public predecisional or confidential commercial information, which is exempt from disclosure to the public within the United States. FDA considers maintaining the confidential nature of these materials to be extremely important. My agency further understands that disclosure by the recipient government of the information contained in these documents could be a criminal violation of federal law and could seriously jeopardize any further cooperative interactions between FDA and the recipient government counterpart organization.

Therefore, _____
(agency) certifies that it:

1. has the authority to protect the non-public predecisional or confidential commercial information from public disclosure,
2. if requested, has attached copies of the relevant statutes, regulations, court decisions, or other documents that establish this authority,
3. will not disclose the information without the written permission of the submitter of this information or a written statement from FDA that the information no longer has non-public status,
4. has listed the names and obtained the signatures of the _____(number) state/local government agency officials or employees who are authorized to have access to the exchanged information and who have agreed to be bound by this agreement,
5. will not reveal the requested non-public FDA information to any other person whose name does not appear on the supplemental page(s),
6. will promptly inform FDA of any efforts made to obtain this information from the _____ (agency) by subpoena, court order, or other compulsory process, and
7. if different from the undersigned, has designated _____ (printed name, title) to receive the non-public information at _____ (address, telephone, facsimile). My agency recognizes that FDA prefers that at least one individual be

commissioned under 21 U.S.C. 372 of the Federal Food, Drug, and Cosmetic Act, and that person be the responsible party for receiving and maintaining this information.

_____ _____

Signature Date
of state/local government official
Print or type the following:
Name of government official:

_____

Title of government official:

_____

Name of agency:

_____

Address:

_____

Telephone and facsimile:

_____

NAMES AND TITLES OF ADDITIONAL PERSONS WITHIN _____, WHO ARE AUTHORIZED TO REVIEW THE NON-PUBLIC PREDECISIONAL OR CONFIDENTIAL COMMERCIAL OR INFORMATION PROVIDED BY FDA:

Print or type the following:
Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

Name of government official:

_____

Title of government official:

_____

EXHIBIT 8-14

INTERNAL MEMORANDUM REQUESTING FURTHER DELEGATION OF AUTHORITY
AND/OR DETERMINATION TO DISCLOSE CONFIDENTIAL COMMERCIAL INFORMATION
TO STATE OR LOCAL GOVERNMENT

(DATE)

FROM: (Insert Name of Person Requesting the Further Delegation or Determination)

SUBJECT: Further Delegation of Authority and/or Determination to Disclose Confidential Commercial Information to State or Local Government

TO: Designee in 21 C.F.R. 5.23 (a)(10)(i) through (vii)

On _____ (date)
_____ (name of state or local government agency) requested the following confidential commercial information:

_____
_____
_____
_____
_____
_____.

In accordance with 21 C.F.R. 5.23 and 20.88, the purpose of this memorandum is to request your authorization regarding the items checked below.

_____1. Delegation of Authority.

Delegation of authority from you to _____ (name of person in Center/Office) or his or her designee to release confidential commercial information described above after FDA receives written authorization for the release from the sponsor.

_____2. Determination Regarding Release of Certain Confidential Commercial Information.

In accordance with 21 C.F.R. 5.23 and 20.88, this memorandum requests your authorization to release the confidential commercial information described above to_____. The information is normally released only

after FDA receives written authorization for the release from the sponsor of the confidential commercial information.

In rare situations, such as where the sponsor has refused to consent to the release of the confidential commercial information or where consent is impractical (for example, consent from the sponsor would be impractical where the confidential commercial information might be relevant in pending regulatory actions against the sponsor), FDA may disclose confidential commercial information to a state or local government if FDA determines that disclosure would be in the interest of public health by reason of the state or local government's possessing information concerning a product's safety, efficacy, or quality or information concerning an investigation.

In this instance, the sponsor has (check one):

_____ consented to the release of the confidential commercial information described above (the sponsor's written consent is attached);

_____ refused to consent to the release of the confidential commercial information described above; or

_____ has not been asked to consent to the release of the confidential commercial information described above. Consent was not sought because ________________________________

____

____

____

____

___________________.

Consequently, we request that you determine whether disclosure of the confidential commercial information may occur, without the sponsor's consent, on the grounds that disclosure would be in the interest of public health by reason of the state or local government's possessing information concerning the safety, efficacy, or quality of a product, or information concerning an investigation.

(Signature)

PLEASE INDICATE CONCURRENCE OR NON-CONCURRENCE BY CHECKING THE APPROPRIATE ITEMS:

1. I AGREE ______, DO NOT AGREE _________ TO DELEGATE AUTHORITY TO _________________________________ (NAME) TO RELEASE CONFIDENTIAL COMMERCIAL INFORMATION AFTER THE SPONSOR PROVIDES WRITTEN AUTHORIZATION FOR SUCH RELEASE.

_____

[Signature of Designee in 21 C.F.R. 5.23(a)(10)(i) through (vii)]
Date
Title of Designee

2. I DO _____, DO NOT _____ DETERMINE THAT PUBLIC HEALTH REASONS EXIST THAT WARRANT DISCLOSURE OF THE CONFIDENTIAL COMMERCIAL INFORMATION IN THE ABSENCE OF SPONSOR AUTHORIZATION.

_____

[Signature of Designee in 21 C.F.R. 5.23(a)(10)(i) through (vii)]
Date
Title of Designee
cc: Designee

EXHIBIT 8-15

INTERNAL MEMORANDUM REQUESTING DETERMINATION TO DISCLOSE NON-PUBLIC PREDECISIONAL INFORMATION TO STATE OR LOCAL GOVERNMENT

(DATE)

FROM: (Insert Name of Person Requesting the Further Delegation or Determination)

SUBJECT: Authorization to Disclose Non-Public Predecisional Information to State or Local Government

TO: (Insert One Title) Deputy Commissioner for Policy, Associate Commissioner for Policy Coordination, or the Director, International Policy, Office of Policy

On _____ (date)
_____ (name of state or local government agency) requested the following non-public predecisional information:

_____
_____
_____
_____
_____
_____.

In accordance with 21 C.F.R. 20.88(e)(1), the purpose of this memorandum is to request your authorization release this information for the following reasons:

_____
_____
_____
_____
_____
_____
_____.

(Signature)

CONCURRENCE/NON-CONCURRENCE:

I DO _____, DO NOT _____ AUTHORIZE DISCLOSURE OF THE PREDECISIONAL INFORMATION DESCRIBED ABOVE.

_____

(Insert title of addressee) Date

cc: W. Schultz HF-22, W. Hubbard HF-11, L. Horton HF-23

EXHIBIT 8-16

STATEMENT (MEMORANDUM TO THE RECORD) THAT
REQUESTED INFORMATION NO LONGER HAS NON-PUBLIC STATUS

(DATE)

FROM: (Name of Appropriate Designee)

On _____ (date) FDA sent non-public records to _____ (name of state or local government agency). The non-public records are described below:

_____
_____
_____
_____
_____.

Pursuant to 21 C.F.R. 20.88 and the commitment it provided, on _____, the state or local agency sent a written request for a determination that the records no longer have non-public status so it can disclose the information.

THE RECORDS DO _____ DO NOT _____ HAVE PUBLIC STATUS FOR THE FOLLOWING
REASONS:_____
_____
_____
_____
_____

(Signature)

EXHIBIT 8-17

MODEL LETTER NOTIFYING REQUESTER THAT THE RECORDS NO LONGER HAVE NON-PUBLIC STATUS

FOR OFFICIAL USE ONLY

(Date)

(Name and address of requester)

Dear _____:

On _____, the Food and Drug Administration (FDA) sent _____ (name of requesting state agency) non-public records. This letter responds to your _____(date) request for a determination that the records described below no longer have non-public status.

(Insert title of non-public document)

FDA has determined that the non-public records (select one) continue to have non-public status and should not be disclosed to the public according to the terms of the "Certification: State and Local Government Statement of Authority and Commitment to Not Disclose" that your agency signed on _____, and 21 C.F.R. 20.88, OR no longer have non-public status.

If you have any questions, please contact me at (insert address, phone number, or electronic mail address).

Sincerely,

(Name of Appropriate FDA Designee)

cc: Name of sponsor, if applicable

bcc: HFC-150
(Name of any participating FDA component)

EXHIBIT 8-18

MODEL SPONSOR'S AUTHORIZATION TO RELEASE CONFIDENTIAL COMMERCIAL AND/OR TRADE SECRET INFORMATION TO A STATE/LOCAL GOVERNMENT AGENCY

(SPONSOR SHOULD PREPARE ON ITS LETTERHEAD)

Freedom of Information Staff
Attention: _____(Name and Title)
Center for _____
(Address)

RE: _____ (Name of Regulated Product, Including Active Ingredient for a Drug Product)

_____ (Application Number) _____(Date of Approval)

Dear _____:

On behalf of_____, the sponsor of the above-referenced regulated product, I hereby consent to disclosure of the following documents by the United States Food and Drug Administration (FDA) to the _____ (name of requesting state/local agency) solely for the purpose of _____.

I understand that the documents may contain confidential commercial or financial information, within the meaning of 18 U.S.C. 1905, 21 U.S.C. 331(j), and U.S.C. 552(b)(4) or other information that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosing the documents to _____ (name of requester).

Documents to be disclosed: (list them or describe them accurately):

Consent is given to the documents being sent without deletion of confidential commercial or trade secret information.

As indicated by my signature, I am the authorizing official for the sponsor and my full name, title, address, telephone number, and facsimile number are set out below for verification. A copy of this letter is being sent to the state/local agency requesting the information.

Sincerely,

_____
(Signature)

_____
(Printed name)

_____
(Title)

_____
(Telephone Number)

_____
(Facsimile Number)

cc: Mr. Richard Barnes, HFC-150
(Name of state/local agency)

EXHIBIT 8-19

MODEL LETTER TRANSMITTING NON-PUBLIC PREDECISIONAL OR CONFIDENTIAL COMMERCIAL INFORMATION

FOR OFFICIAL USE ONLY

(Date)
(Name and address of requester)
Dear _____:

This letter responds to the _____ (name of requesting agency) request dated _____ for information from the Food and Drug Administration (FDA). I am enclosing the following document(s), which contain non-public predecisional or confidential commercial information.

(Insert title of non-public document)

This non-public information is provided for official use only and should be used according to the terms of the "Certification: State and Local Government Statement of Authority and Commitment to Not Disclose" that your agency signed on _____, and 21 C.F.R. 20.88, which provided that the requesting agency maintain the confidentiality of this material until either the sponsor provides you with written permission to disclose or the FDA provides a written statement that the information no longer has non-public status. Further this information may be reviewed by only those persons whose names were provided in the Certification/Commitment.

If you have any questions, please contact me at (insert address, phone number, or electronic mail address).

Sincerely,

(Name of Appropriate FDA Designee)

cc: Name of sponsor, if applicable

bcc: HFC-150
(Name of any participating FDA component)

Initial EFOIA Guidance

Introduction

This is initial guidance to meet an immediate need in ORA component offices for implementation of the Electronic Freedom of Information Act (EFOIA). Policy and procedure in this area is rapidly changing. Additional information and guidance will be issued as it is developed. Any comments, or suggestions for improvement or other changes should be sent to Shari Sheehan, OE/DCP, HFC-230, 301-827-0412.

* Information marked with an asterisk, "*," is for Information Resource Managers or other such technical computer resource personnel involved in the implementation of EFOIA.

EFOIA implementation

As of March 31, 1997, the law required Federal agencies to make reasonable efforts to furnish documents under the EFOIA in electronic format upon request. As of November 1, 1997, it also requires that frequently requested documents created on or after November 1, 1996, be placed on display in an "electronic Reading Room" on the Internet (see section below on "frequently requested" documents). ORA intends to establish a consistent procedure for systematic storage of, and when necessary, electronic redaction of documents, including the "core" records described in the next section. An integral part of efficiently implementing EFOIA is to establish a document management system that will facilitate the flow of documents electronically among the various ORA and FDA component offices and to store them in a manner that makes retrieval easier. Effective immediately, create and save documents electronically as described in this Guidance.

Document creation and storage; "core" records

Guidance for creating and storing documents, and establishing a "core' set of records

- Create documents with word processing software and store them electronically in the same format in which they were created. At a minimum, i.e. a "core" set of records, the following documents should be created and/or stored electronically (if they were not created electronically or the electronic version was not kept, they will need to be scanned into an electronic form):
- Establishment Inspection Reports (EIRs); Memos of Investigation; Inspectional Observations (FDA 483s); and Warning Letters (W/Ls).
- Correspondence issued to regulated industry or the public;
- Any other regulatory document that was created electronically (examples: Collection Reports (C/Rs); Analyst Worksheets; Affidavits; Consumer Complaints; etc.); and

"Core" records (continued)

- Frequently requested documents, which may include important policy statements.

The component office may add to the "core" set of records as appropriate.

EFOIA implementation guidance

- Each component office should provide for systematic storage and electronic redaction of documents which are created and/or stored electronically.
- At a minimum, each office should have a shared file system on a VAX or other server to store final electronic versions and redacted final electronic versions, and to be able to retrieve both in a reasonable manner.
- Documents should be made secure from alteration or deletion.
- Access to the shared files should be as secure as the paper or hard copy files.
- Original documents should be stored in their native format; i.e., if an EIR was created in WordPerfect 6.X, then it would be stored as a WordPerfect 6.X file. EIRs and FDA 483s created with Turbo EIR v.X would be stored as required by that application.
- Documents that are scanned to create an electronic version should be saved as a Portable Document Format (PDF) file.

Document conversion and storage

Converting, creating or storing a document in PDF, or ASCII text or word processing text

- FDA should disclose a redacted record in a format that will ensure that deleted material may not be retrieved by manipulation. PDF or ASCII text best ensures that deleted information cannot be undeleted when an electronic version is provided.

Benefits of Portable Document Format

The benefits of creating and storing information in PDF are:

- universal user access through use of free Adobe Acrobat Reader software;
- reduction of the risk of alteration of the files after receipt by the public;
- portability of redacted files to the "electronic reading room" or elsewhere on an FDA Internet site; and
- preservation of the "look" (italics, underlines, tables, graphics) of the original documents.

Electronic document file structure guidance

These are topics to consider when creating a file structure for electronic documents

- When creating a filing index structure, consider the categories of documents that must be routinely created and/or saved electronically. The "core" set of records (see "Document creation and storage' 'core' records") should be routinely created and/or saved electronically.
- Establish a file structure on the shared drive that will ensure easy access by district personnel for filing, retrieving, and redacting electronic records.

File structure naming guidance

Naming a record in the file structure

- Once a single, centralized file structure is established, the ORA component should establish a uniform naming convention.
- An example of a naming convention for both directories and file names is set out below:

District Name
EIRs (or Memos, or Letters, or FDA 483s, or W/Ls, etc.)
FY 98
Original (or FOI)
File Name *
Activity Date
* Use of long file and short file names could be considered, example:
Long File Name = Name of the Firm
Short File Name = Date of the Inspection, date W/L sent, etc.

- The standardized file extensions based on the original electronic format should be used:

WordPerfect 5.X - .wpc
WordPerfect 6.X - .wpd
Word - .doc
Adobe Acrobat - .pdf

- Other standardized extensions may be obtained by contacting the Division of Information Systems, HFC-30.

*** Maintaining the EFOIA shared drive**

Guidance on maintaining the shared drive for EFOIA implementation.

- The Information Resource Management Directors of the Regional Computer Centers are responsible for establishing and maintaining the district shared drives for electronic document storage and retrieval.

*** Maintaining the shared drive** (continued)	• They are also responsible for assisting with the establishment of files, file structures, naming conventions and the process to be used for adding files to the shared drive.
Saving the final version	Saving the final version of an electronic document. The final electronic version of any document is that electronic version that reflects the final printed and signed hard copy document. You are encouraged to delete prior draft versions when the document is final.
Putting documents on Internet	To put a document on the Internet because you expect to receive multiple FOI requests, contact your regional or division representative to the ORA Internet Working Group.
General response guidance	If a requestor wishes to have a document in an electronic form (microfiche, floppy diskette, etc.) or format (wordprocessing, database, etc.), and if the record is readily available in that form or format, then it is the component office's responsibility to provide it, ensuring that non-public information is redacted and unretrievable by the requestor. If the record is not readily reproducible in that form or format, but is readily reproducible in a different form or format, the requestor should be contacted to let him or her know what is available for his or her consideration. The requestor may also be informed if the information is available on FDA Internet site. However, availability on the FDA Internet site does not remove the obligation to provide requested information in electronic form or in hard copy if that is what the requestor wants.

Responding to EFOIA requests	Handling routine requests
	
	• If you receive a request for a document in electronic format, AND the document (a) was prepared in WordPerfect or Word, AND, (b) contains NON-PUBLIC information, BUT, © no electronic copy was saved:
	
	  • Deletions should be shown by physically obscuring or removing the nondisclosable information, covering the text or figure with opaque ink or redacting tape, or by describing in writing the extent of the deletion,
	  • scan the document,
	  • save it in Portable Document Format (PDF) and put brackets around the space that is left after the words were redacted. (Refer to March 28, 1997 memorandum on EFOIA Interim Guidance, Attachment D).

Electronic documents

If you receive a request for a document in electronic format, AND the document: (a) was prepared in WordPerfect or Word, AND, (b) contains NON-PUBLIC information, AND, (c) the electronic version was saved:

- Access the electronic version on the shared drive, remove all NON-PUBLIC information that is protected from disclosure by a FOIA exemption,
- clearly indicate the extent of the deletion, this may be done by using special characters or other indicators
- then save the redacted document under a new file name into the separate shared FOI directory.
- Copy the redacted document to a clean diskette.

Guidance regarding "frequently requested" documents

Effective March 31, 1997, FDA was required to place additional records that were created on or after November 1, 1996, and for which FDA has received or expects to receive subsequent requests ("frequently requested" documents) in its Reading Room. On November 1, 1997, FDA must have all Reading Room records created by the Agency on or after November 1, 1996, available electronically. That is, FDA will place the records in the Reading Room on the Internet on or before November 1, 1997.

At this time, ORA considers a frequently requested document to be one that has been or is expected to be requested three or more times. Documents that were created *before* November 1, 1996, and that are the subject of multiple requests *may* be put on Internet, but are not *required*, as part of the electronic Reading Room, to be put on Internet.

How to handle "frequently requested" documents

This is guidance on how to process documents that meet the frequently requested criteria.

- If a document meets the frequently requested criteria, AND whether or not you have disclosed it, then not only must a copy be kept of the electronic version (redacted if required), the following MUST be sent to the FDA FOI Office (HFI-35) to be used in the future for "fill froms:"

  - A paper copy of the redacted document,
  - A redacted version in PDF or ASCII on diskette,
  - An Index Form, required as of March 31, 1997 (See March 28, 1997 memorandum, Attachment A).

A copy of the Index Form should also be sent to Office of Enforcement/Division of Compliance Policy, HFC-230, Shari Sheehan.

ORA EFOIA Guidance #2, March 5, 1998

1. Introduction

2. Administrative Issues

   A. Defining an ORA "component" office

   B. Receiving a banyan or email FOIA request

   C. Scanning a handwritten or photocopied record

   D. Retaining a paper copy of a record that you sent to a requester in electronic form

   E. Assessing a fee for a record generated or transmitted electronically

   F. Sending a copy of a record to HFI-35

   G. Putting a record on the Internet

3. Important Information about Warning Letters

4. Responsive Records to the Requester

   A. Providing the requested form or format

   B. Safeguarding against unintended retrieval of redacted information

5. Denial Recommendations and the "Denials" Process

   A. Narrowing the FOIA request

   B. Preparing a denial recommendation

   C. Submitting a denial recommendation

Attachment A: Chart for fee calculations
Attachment B: Model letter identifying available form/format or that the record is on Internet
Attachment C: Model denial recommendation

1. Introduction

This document is the second in a series of guidances to assist Office of Regulatory Affairs (ORA) offices in implementing the Electronic Freedom of Information Act (EFOIA). The Office of Enforcement's (OE) Division of Compliance Policy (DCP), HFC-230, is coordinating EFOIA implementation efforts in ORA, and has prepared this Guidance in consultation with OE's Division of Information Systems, HFC-30, other ORA offices and divisions, and the FOI Staff (HFI-35).

The first Guidance (ORA EFOIA #1) issued on October 23, 1997, and DCP has received some questions about the procedures. This Guidance addresses many of those questions and provides additional information for your consideration.

Please send any comments on EFOIA implementation or on this Guidance to Shari Sheehan, DCP, HFC-230, 301-827-0412; FAX 301-827-0482.

2. Administrative Issues

2. A. Defining an ORA "component" office

What is meant by an ORA component office? ORA strives to improve consistency among all its offices when implementing EFOIA. Therefore, ORA, as a whole, is a component as it relates to general procedures regarding file name configuration, responding to EFOIA requests, and, to the greatest extent possible, other aspects of implementing EFOIA.

In other matters set out in ORA EFOIA #1, such as saving to a main file server, a component may necessarily be a Region or a District office. As stated in ORA EFOIA #1, each ORA office should have a shared file system on a VAX or other server to store unredacted and, if issued, redacted, final electronic versions, and to retrieve both versions readily. The District offices, at this time, have different computer capabilities. Until all of ORA's District offices have similar computer capabilities, however, each Region should encourage consistency among its District offices.

2. B. Receiving a banyan or email FOIA request

FDA policy is to not accept banyan or email FOIA requests.

The FOI Staff is neither equipped nor has the personnel to handle those types of requests at the present time. This policy may change in the future, if the FOI Staff implements a comprehensive electronic document management system.

If you receive a banyan or email request, ask the requester to send the request by facsimile or postal service.

Normally, you would not transmit a record to a requester by banyan or email. However, at the option of the District office, if the FOIA requester specifically states that he/she

wants the record transmitted by banyan or email, the District office may transmit the redacted record in that form.

2. C. Scanning a handwritten or photocopied record

When practical, you are encouraged to discontinue handwriting documents and start creating and storing electronically those records.

Scan a handwritten or photocopied record that previously existed in that format, such as exhibits to an Establishment inspection Report (EIR), only if:

-- you receive a FOIA request for the record in electronic form, and/or,

-- the record is going on the Internet, as part of the electronic reading room or in FDA s discretion.

2. D. Retaining a paper copy of a record that you sent to a requester in electronic form

You need not print a paper copy, as *your office's file copy*, of each record you send to a requester in an electronic form.

2. E. Assessing a fee for a record generated or transmitted electronically

Refer to the table below for fees that ORA may charge a FOIA requester when ORA generates or transmits a document electronically. See also the *Regulatory Procedures Manual* (August 1997), Chapter 8, Subchapter on Freedom of Information Act (FOIA), which sets out routine fee and billing considerations on pp. 353-355.

ORA COMPUTER-RELATED CHARGES UNDER EFOIA

Activity/Supplies	Charge
Form: Paper (such as printouts)	$0.10 a page
Form: Diskette	$1 a diskette
Form: Microfiche	$0.50 a microfiche
Form: Copying a diskette	$3.50 a diskette *(plus the $1 charge/diskette)*
Form: CD-ROM	Price not available at this time
Computer Time: DIS Minicomputer	$10 a run *(Note: There might be multiple runs in a single request.)*

Computer Time: PC	No charge	
Contractor Time: *(Note: FDA may determine that it is reasonable to have a contractor provide services for duplication, such as preparing microfiche copies of records.)*	Actual charge	
Employee Time: *(To the nearest 1/4 hour)*	GS 1 - 8:	$14 an hour
	GS 9 - 14:	$29 an hour
	GS 15:	$52 an hour

Attachment A is a chart to assist in calculating fees.

FDA may charge a requester a contractor's actual fee if one was used to compile the response.

Of records FDA generates, an ORA district or headquarters office/division is responsible for sending only that record that it originated. In that way, especially when HFI-35 sends the request to multiple offices, ORA hopes to reduce the likelihood of sending, and charging for, duplicate copies of the same record to the requester.

Each ORA office is responsible for obtaining its supplies, including diskettes.

2. F. Sending a copy of a record to HFI-35

Generally, send HFI-35 the copies of records as set out below. One or more of the following items may apply for a record. This information is subject to change as FDA has more experience with implementing EFOIA.

(Note: This "bullet" revises the instructions in ORA EFOIA #1, p. 5.) For a record that is on the Internet because it is part of the electronic reading room (i.e., "frequently requested"), send HFI-35:

-- a paper copy of the redacted record, or,
-- if the record was transmitted in electronic form such as by diskette or microfiche, send either the paper copy or a diskette of the redacted record. The diskette may be in PDF or ASCII. If you choose ASCII, and the record was signed, indicate the signature by /s/ or "signed by" in the signature line. And,
-- a completed index form (see Attachment A-1 of the March 28, 1997 memorandum from James O'Hara to others).

For a record, other than a Warning Letter, that is on the Internet but is *not* part of the electronic reading room, send HFI-35:

-- a paper copy of the redacted record, or,
-- if the record was transmitted in electronic form such as by diskette or microfiche, send either the paper copy or a diskette of the redacted record. The diskette may be in PDF or ASCII. If you choose ASCII, and the record was signed, indicate the signature by /s/ or signed by in the signature line.
-- No completed index form is necessary.

For a Warning Letter that HFI-35 routinely puts on the Internet:

-- a paper copy of the redacted record only.
-- No completed index form is necessary.

For a record that is transmitted in electronic form such as diskette or microfiche,

-- a paper copy of the redacted record, or,
-- if the record was transmitted in electronic form such as by diskette or microfiche, send either the paper copy or a diskette of the redacted record. The diskette may be in PDF or ASCII. If you choose ASCII, and the record was signed, indicate the signature by /s/ or "signed by" in the signature line.
-- No completed index form is necessary unless the record is also part of the electronic reading room.

It may not be possible for HFI-35 to identify a "fill from" for the above records before it sends the request to the appropriate ORA office. However, HFI-35 will complete any "fill from" that ORA subsequently brings to their attention for the above records.

Please send Shari Sheehan a copy of any completed index form at the same time it is forwarded to HFI-35. In this way, DCP will be aware of what documents are or will be on the Internet as part of the electronic reading room.

2. G. Putting a record on the Internet

Records in FDA's FOIA "electronic reading room" are on the Internet. (At this time, ORA's standard for a record for the electronic reading room is one that either has been or is expected to be requested three or more times.)

Generally, once identified, ORA will put a document on the Internet (whether or not the document is part of the electronic reading room). Until further guidance issues, please contact your Regional or Division representative to the ORA Internet Working Group if you are interested in putting a record on the Internet.

Some District offices have the capability of putting documents on the Internet. DCP plans to provide guidance to those District offices in the future.

ORA is considering what other records should routinely be put on the Internet. One benefit to ORA of properly redacted records on the Internet is to provide that alternative to

FOIA requesters who have the desire and capability to access requested documents available on the Internet. Statistics compiled by HFI-35 indicated a decrease in FOIA requests in FY 97 directly attributable to the fact that at least one Center was putting more records on the Internet.

Attachment B is a model letter to notify a requester about FDA's available form/format. However, the letter also may be used to give the requester the Internet address (URL) of the requested document. Availability on the Internet does not remove ORA's obligation to provide the requested record in another form/format if that is what the requester prefers. Modify the letter as appropriate to include the Internet address of the available record.

-- The letter consists of two pages. ORA should complete as much of the information on both pages as possible, and send both pages to the requester. If the requester still is interested in obtaining the requested record, but is not interested in retrieving it from the Internet, he or she is expected to complete page two of the letter, and return it to FDA.

3. Important Information About Warning Letters

HFI-35 puts redacted Warning Letters on the Internet.

At this time, send HFI-35 a paper copy only of the redacted original, and, if appropriate, the amended Warning Letter. Send the Letter(s) to them within one week of issuance.

-- If you know that a Warning Letter not yet on the Internet will be amended, alert HFI-35 as soon as possible. They will refrain from putting the original Warning Letter on the Internet and will await the amended Warning Letter. If the original already is on the Internet, HFI-35 will remove it when it receives the amended Warning Letter, and will put the amended one on the Internet instead.

-- HFI-35, upon notice from the FOIA Officer, can treat a subsequent request for a copy of that record as a "fill from."

-- HFI-35 puts the signed version of the Warning Letter on the Internet. Therefore, until further notice from HFI-35, include the signature of the FDA official who signed the Warning Letter.

-- Send HFI-35 a clear, legible copy of the Warning Letter, because they have to scan in the record. Poor quality photocopies will not scan, which may result in a delay in getting the record on the Internet.

Send a paper copy of the *unredacted* Warning Letter to OE's Division of Management and Operations (HFC-210) at the same time you send a copy of the redacted Warning Letter to HFI-35.

Send HFI-35 no other correspondence or explanation with the Warning Letter, because only the redacted Warning Letter will be put on the Internet. At this time, the firm's written response(s) to the Warning Letter will not be put on the Internet. EFOIA does not require FDA

to put the response on the Internet, because it is not a document *created by* a federal government agency (even if the document is frequently requested). This policy may change in the future.

Unlike other documents that go on the Internet, you need not complete and send HFI-35 and HFC-230 an index that lists the Warning Letter.

Ensure that the Warning Letter is properly redacted--neither over- or under-redacted.

Ensure that only the appropriate "cc"s are on the redacted copy of the Warning Letter that goes to HFI-35. That is, only that "cc"s that are on the letter that issued to the firm should appear, and even those MAY need to be redacted. For example, the name of the manufacturer or the repacker may need to be redacted as confidential commercial information. (Generally, names that reflect either FDA internal review and tracking or "bcc"s should not be on the original of the Warning Letter at the time FDA issues it to the firm.)

4. Responsive Records to the Requester

4. A. Providing the requested form or format

The EFOIA provides that an agency make records available in the form (microfiche, diskette, etc.) and format (word processing, database, etc.) identified by the requester, regardless of how the record already exists, when the existing record is "readily reproducible" in the requested form or format with reasonable efforts.

Each request should be handled on a case-by-case basis to determine what effort will be involved to satisfy the requester. EFOIA requires that FDA use reasonable effort to disclose the record in the requested form or format. Refer to Attachment B of the March 28, 1997, memorandum and internal EFOIA guidance from James O'Hara, III, to Associate Commissioners and others for more guidance on the questions you should consider when determining what is "reasonable effort."

For example, if a document is created and stored in Word Perfect 6.0, but the requester asks for the document in Word Perfect 5.1, with reasonable effort, you could (and should) convert the document to Word Perfect 5.1.

Attachment B is a model letter to let the requester know when you cannot, with reasonable effort, provide the document in the requested form or format. Modify the letter as appropriate to include the available forms/formats.

-- The letter consists of two pages. ORA should complete as much of the information on both pages as possible, and send both pages to the requester. The requester is expected to complete page two of the letter, and return it to FDA, if he or she is interested is selecting one of FDA's suggested forms or formats.

Maintain statistics on the number of requests for particular forms and formats (see Attachment B, item 5, of the March 28, 1997, memorandum). This information may assist ORA

in determining how best to obtain the technical capability, if possible, to fulfill the most frequently requested forms and formats.

4. B. Safeguarding against unintended retrieval of redacted information

FDA should disclose a redacted record in a format that will ensure that deleted material cannot be retrieved by manipulation.

Portable Document Format (PDF) or ASCII text best ensures that deleted information cannot be undeleted when an electronic version is provided to a requester. (See ORA EFOIA #1 for more information on the benefits of PDF.) One way to accomplish this is to redact a paper copy of a requested record, then scan the redacted version, which will result in PDF.

FDA is exploring the use of commercial redaction software that has the capability of redacting a record in a way that deleted information cannot be subsequently retrieved. In January 1998, HFI-35 asked DCP to identify four District offices to participate in a pilot of one of the available redaction software products. The following District offices will participate: Atlanta, Chicago, Detroit, and San Francisco.

5. Denial Recommendation and the "Denials" Process

5. A. Narrowing the FOIA request

FDA issues approximately 400 denials a year, of which approximately 300 are from ORA. Most of the 300 denials are related to EIR's.

The denials are recommended by offices throughout ORA in a recommended denial memorandum that is reviewed by Les Weinstein, Esq., Denials Officer, HFI-35. Attachment B is a copy of a model denial recommendation.

Denial recommendations are time consuming for all involved. Therefore, contact a FOIA requester to inquire if he or she is interested in amending the request to narrow it to only those items that are disclosable. For example, a request may be for an EIR and a related 483. If the EIR is not disclosable because the investigation is open, but the 483 is disclosable, the FOIA requester could amend the request and narrow it to only the 483. In that way, there is no need to prepare a denial recommendation for the EIR.

Each request amended for this purpose generally means one less denial to be recommended, reviewed, finalized, and issued. Routine use of this approach is expected to result in fewer denial recommendations. Please see *Regulatory Procedures Manual* (August 1997), Chapter 8, subchapter on Freedom of Information Act (FOIA), p. 352, for a more detailed discussion of this approach.

5. B. Preparing a denial recommendation

Consider the following information as you prepare a denial recommendation:

Be sure you read the request very carefully so you clearly understand what it is the requester wants. When you are clear about what the requester wants, make sure that you have searched for and accounted for each record requested.

If you have determined that one or more of the requested records is not disclosable, have you contacted the requester to notify him or her:

-- about the possibility that part or all of a record may be protected from disclosure by a FOIA Exemption, and

-- to inquire as to whether he or she wants to amend the request to only disclosable records?

For each record requested that is disclosable, have you either enclosed it in your response to the requester, or, if not enclosed, given the reason why (e.g., another component will respond to the request for this particular document)? Do not cite a FOIA Exemption as a reason why the document is not enclosed in the response.

In the denial recommendation memorandum to HFI-35, have you included both the statutory and the regulatory citations for each record or part thereof that you are recommending be denied?

Are the citations correct?

Have you provided a clear and precise reason for why you are applying each Exemption? Ultimately, both the Denials Officer and the requester will need to be able to understand the reason. See Attachment C for a Model Denial Recommendation.

EFOIA now requires FDA to estimate the volume of records being denied. In the denial recommendation, have you included an estimate of the volume of what you are recommending be denied, such as, five pages, three paragraphs, two charts, three linear feet, etc.? You don't have to provide this information, if:

-- it is readily apparent to the requester from the records that are being released (i.e., a partial denial), or

-- in doing so, you would harm an interest that is protected by a FOIA Exemption, e.g., in cases where FDA can neither confirm nor deny the existence of a record (Glomar statement).

Did you document important discussions, including those with the requester, and comments regarding the search for the responsive record? This file of documents/comments could constitute what is known as the administrative record in the event that the matter is

disputed.

5. C. Submitting a denial recommendation

A District FOIA Officer should send the denials package directly to the Denials Officer (HFI-35).

ATTACHMENT A: CHART FOR FEE CALCULATIONS

TOTAL CHARGE:

				For Type		
				C	N	O
1. Hourly Rates for Search and Review (In 1/4 hour increments)	**$14**	**$29**	**$52**			
Search*	_____	_____	_____	**$**_____	**N/A**	**$**_____
Review	_____	_____	_____	_____	**N/A**	**N/A**
2. Duplication:						
Paper: #_____ x 10				_____	_____	_____
Diskettes #_____ x $1				_____	_____	_____
Copying a diskette #_____ x $3.50				_____	_____	_____
Microfiche #_____ x 50				_____	_____	_____
3. Contractor s Actual Charge:				_____	_____	_____
4. Computer Time (DIS Minicomputer): #_____ x $10 a run				_____	_____	_____
5. Special Mailing Charges (Actual)				_____	_____	_____
6. Other Charges:				_____	_____	_____
TOTAL CHARGE (include this in the letter responding to the requester):				**$**_____	**$**_____	**$**_____

Is there a maximum amount requester is willing to pay? **$**_____
(If charges exceed this maximum, requester must approve additional charges.)

Is the TOTAL CHARGE over $250? (Check one) **Yes**_____ **No**_____
(If Yes, prepayment is required.)

Fee Waiver Requested? Yes _____ **No**_____
(If Yes, and charge is under $250, response letter should state: Your request for waiver of fees will be considered by the ACPA.)
(If Yes, and charge is over $250, send the waiver recommendation to the component FOIA Officer, who will forward the recommendation to the FOIA Staff.)

*The FOI Staff will assess each eligible requester (Type C and Type O), a standard agency charge for reading and interpreting a request when invoiced.

ATTACHMENT B: MODEL LETTER IDENTIFYING AVAILABLE FORM/FORMAT OR THAT THE RECORD IS ON INTERNET

(FDA completes page one and, to the greatest extent possible, page two. The requester completes page two.)

Date:

RE: FOIA Request #:_____

Dear ___ (Name of requester)

This letter follows up your _____ (date) request for Food and Drug Administration (FDA) records under the Freedom of Information Act. We are notifying you that FDA: [*Check the appropriate item(s)]*

1. ___ is unable to readily reproduce the response to item ___ of your letter in the requested form/format as indicated below.

Requested Information: _____.
Requested Form/Format: _____.

However, we are able to provide you the requested information in one of the forms or formats set out on page two of this letter. The remainder of your request will be processed separately.

2. ___ is able to provide you the response to item ___ of your letter in the requested form/format. However, the fee for duplication alone, which may include a contractor s actual charge, is $_____. There may be other charges. *(Check this item when the contractor s fee is expensive.)*

3. ____ has put the record on the Internet at _____(Internet address).

Please let us know within thirty days from the date of this letter whether you:

1. intend to amend your FOIA request to receive the information in the form or format you have identified on page two, or

2. for a record on the Internet, prefer to receive the record in either your original or amended requested form or format.

You may indicate your preference and return a signed copy of page two of this letter form by mail or facsimile (insert number). If we do not receive your response within thirty days, we will consider your request as to that item closed.

Sincerely,

(Name and Mail Symbol of FOIA Officer)

Page two **(Page two is completed by the FOIA requester, unless otherwise noted, and sent back to FDA.)**

Date: (completed by requester)

RE: FOIA Request #: _____ (completed by FOIA Officer before sending the letter)

Food and Drug Administration
(Name, Mailing Symbol, and Address of FOIA Officer)
Telephone of FOIA Officer: _____ (completed by FOIA Officer)
Facsimile of FOIA Officer: _____ (completed by FOIA Officer)

Dear FDA FOIA Officer:

In response to your _____ (date) letter, I am: [*Check appropriate item(s)]*

1. ____ rather than retrieving the requested record on the Internet, notifying you that I wish to receive the record _____(identify record) in the form/format that I requested in my original letter dated _____, or as indicated by the amended form/format below, and/or

2. ____ amending my _____ (date) FOIA request to change the form/format of the record _____ (identify record), to the form/format identified below.

3. ____ agreeing to the contractor s actual fee of $_____.

Check one:
Form
____ Paper ($.10 a page)
____ Diskette ($1.00 a diskette)
____ Microfiche ($.50 a microfiche), etc.
Check one:

Format
____ MS Word
____ WP 6.0
____ WP 5.2 Etc.

Please advise me of the charges at _____(requester's address, telephone, facsimile numbers).

_____
(Printed Name of Requester)

_____
(Signature of Requester)

ATTACHMENT C: MODEL DENIAL RECOMMENDATION

DATE:_____, 1998

REQUESTER: Mary Smith, Smith Associates

FROM: Freedom of Information Officer
Florida District (HFR-SE240) 12 Elm St., Providence RI 02906

SUBJECT: F98-XXXXX

TO: Les Weinstein
Denials Officer
Freedom of Information Staff (HFI-35)

DENIAL RECOMMENDATION

The above-referenced FOIA request was for documents regarding XYZ, Inc. of Miami, FL.

We have provided the requester with the 483 dated November 16, 1997. We are recommending denial of the related EIR pursuant to FOIA, 5 U.S.C.
552(b)(7)(A) and 21 C.F.R. 20.64 because of the active investigatory status of the firm. The EIR is a record compiled for law enforcement purposes, and its release could reasonably be expected to interfere with enforcement proceedings.

The firm was issued a Warning Letter on December 15, 1997. The investigatory status will remain open until FDA concludes that no further administrative or regulatory action is dictated.

The EIR consists of five pages.

John Jones

Enclosure

SECTION V

References

Section V

References

In section V This section contains the following FOI related references

THE WHITE HOUSE

WASHINGTON

October 4, 1993

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

SUBJECT: The Freedom of Information Act

I am writing to call your attention to a subject that is of great importance to the American public and to all Federal departments and agencies the administration of the Freedom of Information Act, as amended (the "Act"). The Act is a vital part of the participatory system of government. I am committed to enhancing its effectiveness in my Administration.

For more than a quarter century now, the Freedom of Information Act has played a unique role in strengthening our democratic form of government. The statute was enacted based upon the fundamental principle that an informed citizenry is essential to the democratic process and that the more the American people know about their government the better they will be governed. Openness in government is essential to accountability and the Act has become an integral part of that process.

The Freedom of Information Act, moreover, has been one of the primary means by which members of the public inform themselves about their government. As Vice President Gore made clear in the National Performance Review, the American people are the Federal Government's customers. Federal departments and agencies should handle requests for information in a customer-friendly manner. The use of the Act by ordinary citizens is not complicated, nor should it be. The existence of unnecessary bureaucratic hurdles has no place in its implementation.

I therefore call upon all Federal departments and agencies to renew their commitment to the Freedom of Information Act, to its underlying principles of government openness, and to its sound administration. This is an appropriate time for all agencies to take a fresh look at their administration of the Act, to reduce backlogs of Freedom of Information Act requests, and to conform agency practice to the new litigation guidance issued by the Attorney General, which is attached.

Further, I remind agencies that our commitment to openness requires more than merely responding to requests from the public. Each agency has a responsibility to distribute information on its own initiative, and to enhance public access through the use of electronic information systems. Taking these steps will ensure compliance with both the letter and spirit of the Act.

WILLIAM J. CLINTON

October 4, 1993

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

SUBJECT: The Freedom of Information Act

President Clinton has asked each Federal department and agency to take steps to ensure it is in compliance with both the letter and the spirit of the Freedom of Information Act (FOIA),5 U.S.C § 552. The Department of Justice is fully committed to this directive and stands ready to assist all agencies as we implement this new policy.

First and foremost, we must ensure that the principle of openness in government is applied in each and every disclosure and nondisclosure decision that is required under the Act. Therefore, I hereby rescind the Department of Justice's 1981 guidelines for the defense of agency action in Freedom of Information Act litigation. The Department will no longer defend an agency's withholding of information merely because there is a "substantial legal basis" for doing so. Rather, in determining whether or not to defend a nondisclosure decision, we will apply a presumption of disclosure.

To be sure, the Act accommodates, through its exemption structure, the countervailing interests that can exist in both disclosure and nondisclosure of government information. Yet while the Act's exemptions are designed to guard against harm to governmental and private interests, I firmly believe that these exemptions are best applied with specific reference to such harm, and only after consideration of the reasonably expected consequences of disclosure in each particular case.

In short, it shall be the policy of the Department of Justice to defend the assertion of a FOIA exemption only in those cases where the agency reasonably foresees that disclosure would be harmful to an interest protected by that exemption. Where an item of information might technically or arguably fall within an exemption, it ought not to be withheld from a FOIA requester unless it need be.

It is my belief that this change in policy serves the public interest by achieving the Act's primary objective -- maximum responsible disclosure of government information -- while preserving essential confidentiality. Accordingly, I strongly encourage your FOIA officers to make "discretionary disclosures" whenever possible under the Act. Such disclosures are possible under a number of FOIA exemptions, especially when only a governmental interest would be affected. The exemptions and opportunities for "discretionary disclosures" are discussed in the Discretionary Disclosure and Waiver section of the "Justice Department Guide to the Freedom of Information Act." As that discussion points out, agencies can make discretionary FOIA disclosures as a matter of good public policy without concern for future "waiver consequences" for similar information. Such disclosures can also readily satisfy an agency's "reasonable segregation" obligation under the Act in connection with marginally exempt information, see 5 U.S.C. § 552(b), and can lessen an agency's administrative burden at all levels of the administrative process and in litigation. I note that this policy is not intended to create any substantive or procedural rights enforceable at law.

In connection with the repeal of the 1981 guidelines, I am requesting that the Assistant Attorneys General for the Department's Civil and Tax Divisions, as well as the United States Attorneys, undertake a review of the merits of all pending FOIA cases handled by them, according to the standards set forth above. The Department's litigating attorneys will strive to work closely with your general counsels and their litigation staffs to implement this new policy on a case--bycase basis. The Department's Office of Information and Privacy can also be called upon for assistance in this process, as well as for policy guidance to agency FOIA officers.

In addition, at the Department of Justice we are undertaking a complete review and revision of our regulations implementing the FOIA, all related regulations pertaining to the Privacy Act of 1974, 5 U.S.C. § 552a, as well as the Department's disclosure policies generally. We are also planning to conduct a Departmentwide "FOIA Form Review." Envisioned is a comprehensive review of all standard FOIA forms and correspondence utilized by the Justice Department's various components. These items will be reviewed for their correctness, completeness, consistency, and particularly for their use of clear language. As we conduct this review, we will be especially mindful that FOIA requesters are users of a government service, participants in an administrative process, and constituents of our democratic society. I encourage you to do likewise at your departments and agencies.

Finally, I would like to take this opportunity to raise with you the longstanding problem of administrative backlogs under the Freedom of Information Act. Many Federal departments and agencies are often unable to meet the Act's ten-day time limit for processing FOIA requests, and some agencies -- especially those dealing with high-volume demands for particularly sensitive records -- maintain large FOIA backlogs greatly exceeding the mandated time period. The reasons for this may vary, but principally it appears to be a problem of too few resources in the face of too heavy a workload. This is a serious problem -- one of growing concern and frustration to both FOIA requesters and Congress, and to agency FOIA officers as well.

It is my hope that we can work constructively together, with Congress and the FOIA - requester community, to reduce backlogs during the coming year. To ensure that we have a clear and current understanding of the situation, I am requesting that each of you send to the Department's Office of Information and Privacy a copy of your agency's Annual FOIA Report to Congress for 1992. Please include with this report a letter describing the extent of any present FOIA backlog, FOIA staffing difficulties and any other observations in this regard that you believe would be helpful.

In closing, I want to reemphasize the importance of our cooperative efforts in this area. The American public's understanding of the workings of its government is a cornerstone of our democracy. The Department of Justice stands prepared to assist all Federal agencies as we make government throughout the executive branch more open, more responsive, and more accountable.

Janet Reno

U.S. Department of Justice
Office of Information and Privacy
Washington, D.C. 20530

Executive Order No. 12,600 Issued June 23, 1987

FOIA

By the authority vesting in me as President by the Constitution and statutes of the United States of America, and in order to provide predisclosure notification procedures under the Freedom of Information Act concerning confidential commercial information, and to make existing agency notification provisions more uniform, it is hereby ordered as follows:

Section 1. The head of each Executive department and agency subject to the Freedom of Information Act shall, to the extent permitted by law, establish procedures to notify submitters of records containing confidential commercial information as described in section 3 of this Order, when those records are requested under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, if after reviewing the request, the responsive records, and any appeal by the requester, the department or agency determines that it may be required to disclose the records. Such notice requires that an agency use good-faith efforts to advise submitters of confidential commercial information of the procedures established under this Order. Further, where notification of a voluminous number of submitters is required, such notification may be accomplished by posting or publishing the notice in a place reasonably calculated to accomplish notification.

Sec. 2. For purposes of this Order, the following definitions apply:

(a) "Confidential commercial information" means records provided to the government by a submitter that arguably contain material exempt from release under Exemption 4 of the Freedom of Information Act, 5 U. S.C. 552(b)(4), because disclosure could reasonably be expected to cause substantial competitive harm.

(b) "Submitter" means any person or entity who provides confidential commercial information to the government. The term "submitter" includes, but is not limited to, corporations, state governments, and foreign governments.

Sec. 3.(a) For confidential commercial information submitted prior to January 1, 1988, the head of each Executive department or agency shall, to the extent permitted by law, provide a submitter with notice pursuant to section I whenever:

(i) the records are less than 10 years old and the information has been designated by the submitter as confidential commercial information; or

(ii) the department or agency has reason to believe that disclosure of the information could reasonably be expected to cause substantial competitive harm.

(b) For confidential commercial information submitted on or after January 1, 1988, the

head of each Executive department or agency shall, to the extent permitted by law, establish procedures to permit submitters of confidential commercial information to designate, at the time the information is submitted to the Federal government or a reasonable time thereafter, any information the disclosure of which the submitter claims could reasonably be expected to cause substantial competitive harm. Such agency procedures may provide for the expiration, after a specified period of time or changes in circumstances, of designations of competitive harm made by submitters. Additionally, such procedures may permit the agency to designate specific classes of information that will be treated by the agency as if the information has been so designated by the submitter. The head of each Executive department or agency shall, to the extent permitted by law, provide the submitter notice in accordance with section I of this Order whenever the department or agency determines that it may be required to disclose records:

(i) designated pursuant to this subsection; or

(ii) the disclosure of which the department or agency has reason to believe could reasonably be expected to cause substantial competitive harm.

Sec. 4. When notification is made pursuant to section 1, each agency's procedures shall, to the extent permitted by law, afford the submitter a reasonable period of time in which the submitter or its designee may object to the disclosure of any specified portion of the information and to state all grounds upon which disclosure is opposed.

Sec. 5. Each agency shall give careful consideration to all such specified grounds for nondisclosure prior to making an administrative determination of the issue. In all instances when the agency determines to disclose the requested records, its procedures shall provide that the agency give the submitter a written statement briefly explaining why the submitter's objections are not sustained. Such statement shall, to the extent permitted by law, be provided a reasonable number of days prior to a specified disclosure date.

Sec. 6. Whenever a FOIA requester brings suit seeking to compel disclosure of confidential commercial information, each agency's procedures shall require that the submitted be promptly notified.

Sec. 7. The designation and notification procedures required by this Order shall be established by regulations, after notice and public comment. If similar procedures or regulations already exist, they should be reviewed for conformity and revised where necessary. Existing procedures or regulations need not be modified if they are in compliance with this Order.

Sec. 8. The notice requirements of this Order need not be followed if

(a) The agency determines that the information should not be disclosed;

(b) The information has been published or has been officially made available to the public;

(c) Disclosure of the information is required by law (other than 5 U.S. C. 552);

(d) The disclosure is required by an agency rule that (1) was adopted pursuant to notice and public comment, (2) specifies narrow classes or records submitted to the agency that are to be released under the Freedom of Information Act, and (3) provides in exceptional circumstances for notice when the submitter provides written

justification, at the time the information is submitted or a reasonable time thereafter, that disclosure of the information could reasonably be expected to cause substantial competitive harm;

(e) The information requested is not designated by the submitter as exempt from disclosure in accordance with agency regulations promulgated pursuant to section 7, when the submitter had an opportunity to do so at the time of submission of the information or a reasonable time thereafter, unless the agency has substantial reason to believe that disclosure of the information would result in competitive harm; or

(f) The designation made by the submitter in accordance with agency regulations promulgated pursuant to section 7 appears obviously frivolous; except that, in such case, the agency must provide the submitter with written notice of any final administrative disclosure determination within a reasonable number of days prior to the specified disclosure date.

Sec. 9. Whenever an agency notifies a submitter that it may be required to disclose information pursuant to section I of this Order, the agency shall also notify the requester that notice and an opportunity to comment are being provided the submitter. Whenever an agency notifies a submitter of a final decision pursuant to section 5 of this Order, the agency shall also notify the requester.

Sec. 10. This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

Memorandum

Date March 28, 1997

TO: FDA Senior Staff
District Directors
FOIA Officers
EFOIA Task Force

FROM: James A. O'Hara III, Associate Commissioner
For Public Affairs

Margaret Jane Porter, Chief Counsel

Robert J. Byrd, Deputy Commissioner
For Management and Systems

SUBJECT: Interim Guidance on Implementation of the Electronic FOIA Amendments of 1996

The purpose of this memo is to provide interim guidance on the procedures to follow for implementation of those provisions of the Electronic Freedom of Information Act Amendments of 1996 (EFOIA) that become effective on March 31, 1997. Additional interim guidance will be issued subsequently for those provisions with later effective dates. EFOIA, which was signed into law on October 2, 1996, is intended to facilitate more rapid and convenient citizen access to government information.

On November 20, 1996, an agency-wide EFOIA Task Force was established to advise on the implementation of EFOIA. The work of this group has been invaluable in developing the attached procedures.

The EFOIA provisions that become effective on March 31, 1997, and for which interim guidance is now being issued, are as follows:

1. New category of FOIA "reading room" records and new indexing requirement: Records disclosed in response to a FOIA request that have become, or are likely to become, the subject of subsequent requests must now be available in agencies' public reading rooms and listed in a general index. (See Attachment A.)

2. Honoring form/format requests: Agencies are required to honor a requester's specified choice among existing forms of a requested record and to make "reasonable efforts" to

disclose a record in a different form or format when that is requested and the record "is readily reproducible" in that new form or format. (See Attachment B.)

3. Electronic searches: Agencies are required to make reasonable efforts to search for requested records by automated means, except where doing so would significantly interfere with the operation of the agencies' automated information systems. (See Attachment C.)

4. Redaction and deletion specification: If records are released to a FOIA requester with deletions, agencies must indicate the amount of deleted information at the place in the record where the deletion is being made, if it is technically feasible to do so. (See Attachment D.)

This interim guidance has been developed in consultation with the Office of Information and Privacy at the Department of Justice and the HHS Freedom of Information-Privacy Acts Division. If further guidance is forthcoming from those offices, additional FDA guidance may be provided.

In addition, EFOIA requires agencies to create and maintain through electronic means a handbook for obtaining public information from agencies, and a reference guide describing the major information and record locator systems. We are in the process of making the handbook and the guide available on FDA's Home Page. No interim guidance is necessary for this provision.

The agency plans to revise Staff Manual Guide 2460.7, Procedures for Implementing the Freedom of Information Act, to incorporate the new EFOIA procedures. Until that time, the interim guidance will be in effect.

If you have any EFOIA related questions, please contact Betty Dorsey, Director, or Les Weinstein, Deputy Director, Freedom of Information Staff (HFI-35) via banyan or phone (301-443-1813).

Attachments

ATTACHMENT A

INTERIM GUIDANCE ON THE EFOIA READING ROOM PROVISION

1. PURPOSE

   a. To comply with the FOIA provisions requiring the Agency to place specific categories of records in its public reading rooms;
   b. To potentially obviate the need for future FOIA requests for records that have been previously requested and disclosed and which have been, or are likely to become, the subject of at least two or more subsequent FOIA requests;
   c. To create a general index of those reading room records that have been or are likely to be frequently-requested under FOIA; and
   d. To make those reading room records created by the Agency on or after November 1, 1996 available electronically by November 1, 1997.

2. CATEGORIES OF RECORDS IN THE PUBLIC READING ROOM

   Effective March 31, 1997, FDA will be required to place additional records in one of its two public reading rooms. These records include:

   a. Records that have been previously requested and disclosed under FOIA, and which have been or are likely to become the subject of two or more additional requests. This category will be referred to as "frequently-requested" records.

   b. A general index of "frequently-requested" records.

3. RESPONSIBILITIES

   a. The FOI Staff in the Office of Public Affairs is responsible for:

      (1) Operating the public reading room located in the Office of Public Affairs, Parklawn Building, 5600 Fishers Lane, Room 12A-30, Rockville, MD.;

      (2) Creating and maintaining the Agency's index of frequently-requested records contained in the public reading rooms.

   b. The Dockets Management Branch is responsible for operating the public reading room located in the Park Building, 12420 Parklawn Drive, Room 1-23, and Rockville, MD.

c. Each Component FOI Office now has the following additional responsibilities:

(1) Identifying those records which must be placed in the public reading room because they have previously requested and disclosed under FOIA, and have been or are likely to become the subject of two or more additional requests. This responsibility includes identifying those records which fall into this new reading room category, even if they only exist in some form other than conventional paper form, for example: audiotape, videotape, or some electronic form.

(2) Identifying those records which may be placed in the public reading room because they are likely to be requested three or more times although they have not yet been the subject of a FOIA request. By placing those documents which are likely to become "hot topics" into the public reading room, the Agency will potentially obviate the need for future FOIA requests for these records.

(3) After identifying those frequently-requested records to be placed in an FDA public reading room, you should describe these records using the attached form (or a similar format) and forward the descriptions to the FOI Staff, HFI-35. (See Attachment A-1.) The FOI Staff will use this information to prepare the general index.

(4) For those records identified in accordance with paragraph (c)(1) above, copies of these records should already have been forwarded to the FOI Staff, HFI-35, as part of your response to the initial FOIA request. Rather than resend these records to HFI-35, you should include the official FOI file number when you submit the attached form. (See Attachment A-1.)

(5) Because records identified in accordance with paragraph (c)(2) above have not previously been requested and disclosed under FOIA, copies of these documents must be forwarded to an FDA public reading room. You should contact the Director, FDA FOI Staff, (301) 443-1813, or the Chief, Dockets Management Branch, (301) 443-7542, for additional guidance as to where to send those records.

(6) For those reading room records requiring redaction, EFOIA now requires that the amount of the redaction be indicated on the portion of the record being placed in the reading room. If technically feasible, the extent of the redaction shall be indicated at the place in the record where the redaction was made. See the guidance on Redaction and Deletion Specification (Attachment D).

(7) Reading room records created by FDA (or other federal agencies) on or after November 1, 1996 should be retained in the electronic form in which they were created, in addition to conventional paper form. This will facilitate the Agency's compliance with the additional requirement that, as of November 1, 1997, all reading room records created by the Agency on or after November 1, 1996 be made available electronically. Please indicate on the attached form (See Attachment A-1) whether records are newly created by checking the appropriate box.

Frequent FOIA Request Report

FROM ACTION OFFICE: _____ DATE: _____ _

TO: FDA FOI STAFF, HFI-35

The following records have been requested and disclosed three times or more, or are likely to be requested and disclosed three times or more, and therefore, should be placed in an FDA public reading room. To help identify those records which also will be placed in the FDA's electronic reading room, please place a check mark (✓) in the last column if the record was created by the agency on or after November 1, 1996.

FOI File Number (If applicable)	**Subject or general description of record(s)**	**Created by agency on or after 11/01/96**

Copies of all records in this report should be forwarded to HFI-35, with redactions if appropriate.

INTERIM GUIDANCE ON THE HONORING FORM AND FORMAT PROVISION OF THE ELECTRONIC FREEDOM OF INFORMATION AMENDMENTS OF 1996 (EFOIA).

PURPOSE: to give FOIA requesters their choice among existing forms, including electronic forms, of a requested record and to make "reasonable efforts" to disclose a record in a different form or format of the requester's choice if the record is "readily reproducible" in that new form or format.

1. Definitions

   (a) Form: The defined medium the record is physically incorporated in/on (i.e., paper, floppy diskette, CD-ROM, microfiche).

   (b) Format: The type of electronic record and the specific program used to generate an/or reproduce the record. Examples include:

Wordprocessing:	MS Word, WordPerfect, ascii test
Spreadsheet:	Lotus 1-2-3, MS Excel
Database:	dBASE, Paradox
Graphic	tiff, gif, PDF

2. Component offices throughout FDA shall make reasonable efforts to maintain their records in forms or formats that are reproducible for FOIA purposes.

3. If the component office responsible for responding to a FOIA request maintains a record in more than one form or format, the FOIA requester may choose among the existing forms or formats of the record, so long as the record is "readily reproducible" in the chosen form. In almost all cases, FDA should be able to reproduce any existing form or format of a record for which a requester expresses a preference.

4. If a FOIA requester asks for a record in a form or format not maintained by the component office responsible for responding to the request, the component office must comply with the request if the record is readily reproducible in that form or format with reasonable efforts. In some situations such as where the record already exists in one electronic format and the component office is readily able to convert it to a different electronic format upon request, the component office will be obligated to comply with the request. In other situations, such as where records exist only in paper form and the requester seeks to have them converted to an electronic form, the component office may determine that it cannot readily do so with a reasonable amount of effort.

   (a) The component office, in consultation with information resource management staff, should determine on a case by case basis whether a record can be readily

reproduced, with reasonable efforts, in the electronic form/format requested by weighing the following factors:

- current form/format of the record
- availability of equipment/technology to reproduce and/or convert the record in the requested form/format either in house or by contracting out
- availability of expertise to reproduce/convert the record to the requested form/format
- time required for reproduction/conversion to requested form/format considering the size/complexity of the record
- impact of form/format conversion on the ability to adhere to redaction requirements

(b) The component office may ask another component office or the headquarters FOI Staff (HFI-35) for assistance in converting a record to the requested form. There is no obligation to do this, however because of the decentralized nature of FDA's FOIA program.

(c) The component office should consult with the requester by phone or letter explaining that the information is not available or reproducible in the form/format requested and ask him/her to select from among several form/format options.

5. Each component FOI officer shall compile and maintain statistics on form/format requests: specific form or format specified in request; was the request for a form/format in which the component already maintained the record; was the request complied with; if not, why not and in what form/format was the record provided to the requester? The reasons for these statistics are: the new EFOIA reporting requirements, to be issued by the Department of Justice, may require us to include some or all of this information; these statistics will be helpful in determining the need for any revisions to this interim guidance; and the information may be helpful in assessing the Agency's technological capability to meet the form/format requirements.

ATTACHMENT C

INTERIM GUIDANCE ON THE ELECTRONIC SEARCH PROVISION OF THE ELECTRONIC FREEDOM OF INFORMATION AMENDMENTS OF 1996 (EFOIA)

PURPOSE: to promote electronic database searches and to encourage agencies to expend new efforts in order to comply with the electronic search requirements of particular FOIA requests.

1. Definition

   Search: the review, manually or by automated means, of agency records, including electronic databases, for the purpose of locating those records, if any, responsive to a FOIA request.

2. Each component office shall make "reasonable efforts" to search for records in an electronic form or format, except when such efforts would significantly interfere with the operation of the Agency's automated information system or normal work operations. What constitutes "reasonable" and "significantly interfere" will depend on the particular set of circumstances involved. Electronic searches should be conducted using the most narrowly defined parameters as possible to ensure efficient and accurate data retrieval.

INTERIM GUIDANCE ON THE REDACTION AND DELETION SPECIFICATION PROVISIONS OF THE ELECTRONIC FREEDOM OF INFORMATION AMENDMENTS OF 1996 (EFOIA)

PURPOSE: to give FOIA requesters a clear understanding of how much information has been deleted on the documents they receive and exactly where those deletions have been made, regardless of whether the record they receive is in hard copy or in an electronic form.

When information is being redacted (deleted) from a record that the Agency is going to release in part to a FOIA requester:

1. The amount of information redacted should be indicated where the redaction was made on the released portion of the record.

2. In the unusual situation where indicating the amount of information redacted on the released portion of the document would harm the interest the redaction is protecting (e.g., privacy interest or situations where the response to a requester is that the Agency can "neither confirm nor deny" the existence of a record), then it is not necessary to so indicate.

3. How the deletion specification is done on the form of the record:

   (a) If hard copy (conventional paper copy), a marker (grease pencil) or dark colored graphic editing tape is preferred. If white-out or white correction tape is used, specify how much has been redacted with symbols (e.g., brackets, lines) or descriptive indications (e.g., 3 words, 20 lines, 5 pages).

   (b) If in electronic format, indicate the amount of information deleted at the place in the record where the deletion was made, if it is technically feasible to do so, with electronic markings, symbols or descriptive indications. If it is not technically feasible to indicate the deletions at the exact location in the record where they occur, the deletions may be indicated elsewhere in the record or in the cover letter to the requester. (Since special redaction software may be needed to redact electronic records and indicate where the deletions have been made electronically, the lack of such software is an example of "not technically feasible.") For complex electronic records (e.g., large database), where certain fields have been suppressed, eliminated or not selected, the requirement to visibly indicate such suppression, etc. could be complied with by placing extraneous characters, such as "xxxxxx," in the data field, if it is technically feasible to do so.

4. The above deletion specification requirements also apply to any redacted records placed in the Agency's public reading rooms located at the FOI Staff (HFI-35) and Dockets Management Branch (HFA-305).

MEMORANDUM

April 13, 1998

To: Freedom of Information Officers

From: Director, Freedom of Information Staff, HFI-30

Subject: Multitrack Processing

The 1996 Electronic Freedom of Information Act (EFOIA) Amendments encourage agencies that experience difficulties in meeting the FOIA's time limit to promulgate regulations providing for "multitrack processing" of FOIA requests. The purpose of multitrack processing is to promote faster and more efficient processing of requests by assigning requests to tracks based on the amount of work or time (or both) that is involved in processing the requests. In its draft proposed rule implementing the 1996 EFOIA Amendments, the agency will propose to adopt a multitrack processing system on a component (Center, District Office, etc.) by component basis.

Because the types and complexity of records maintained by FDA differ greatly from one agency component to another; because the nature and volume of FOIA requests received differ greatly from one component to another; and because of the decentralized nature of the agency's FOIA processing systems, each component may decide whether or not it will adopt a multitrack processing system. If a multitrack processing system is not adopted by a particular agency component, that component will process all requests in a single track on a first-in, first-out basis. If a multitrack processing system is adopted, the following apply:

1. A component must establish at least two tracks and may establish more if it desires. Those two tracks are:

   A. Simple -- requests which are simple and can be answered quickly with readily available information. This would be the faster track.
   B. Complex -- requests which are complicated and/or involve voluminous records. These would include requests which require substantive decisions or input in determining releasability, and/or require extensive search and/or redaction of records in order to prepare for release. This would be the slower track.
2. Requests will be assigned to a given track by the agency component responsible for processing the requests based on the amount of work or time (or both) involved in processing the requests.

3. Requests assigned to a given track will be processed on a first-in, first-out basis within that track.

4. If a request does not qualify for the fastest processing track, the requester may be given the opportunity to limit the scope of the request in order to qualify for faster processing.

The EFOIA Amendments require agencies to report the median number of days taken by the agency to process different types of requests. In order to provide this information in an automated manner, the FOI Staff has modified its tracking system to calculate median processing time. Effective immediately, I am asking all components to provide this information to the FOI Staff (HFI-35) by annotating and returning the control sheet that accompanies each request (sample attached) with a copy of the response to the FOI request. For each request processed, indicate whether the request was processed in a single track or a multitrack processing system. If the request was processed in a multitrack system, specify whether the request was processed as a simple or complex request. Please note that control sheets for requests logged prior to April 13, 1998 do not contain the fields related to processing tracks. However, you are asked to provide this information for all requests processed on or after April 13, 1998 by indicating the appropriate track.

The EFOIA Amendments also contain a provision which requires agencies to promulgate regulations authorizing "expedited processing" of a request for records in cases in which the requester demonstrates a "compelling need" or in other cases as determined by the agency. A compelling need exists when:

(1) a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) with respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged federal government activity.

Within 10 days after receipt of a request for expedited processing, the agency must decide whether to grant expedited processing and must notify the requester of its decision. Requests that qualify for expedited processing will be processed **before** all other categories of requests. I will review requests for expedited processing and will contact the appropriate component FOI Officer for a recommendation of whether or not to grant the request for expedited processing.

The FOIA Amendments also require agencies to report median processing time for requests accorded expedited processing. Please provide this information by annotating the control sheet as described above.

FOI Officers who wish to discuss alternative means for providing information concerning processing tracks to the FOI Staff may contact me at 301-827-6567.

We appreciate your cooperation as we continue to implement the 1996 EFOIA Amendments. Further guidelines on these as well as other provisions of the Amendments will be issued at a later date.

Betty B. Dorsey

Attachment

The Freedom of Information Act

5 U.S.C. § 552, As Amended By

Public Law No. 104-231, 110 Stat. 3048

Below is the full text of the Freedom of Information Act in a form showing all amendments to the statute made by the "Electronic Freedom of Information Act Amendments of 1996." All newly enacted provisions are in boldface type.

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public--

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying--

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the

adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; ~~and~~

(C) administrative staff manuals and instructions to staff that affect a member of the public;

(D) copies of all records, regardless of form or format, which have been released to any person under paragraph (3) and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; and

(E) a general index of the records referred to under subparagraph (D);

unless the materials are promptly published and copies offered for sale. **For records created on or after November 1, 1996, within one year after such date, each agency shall make such records available, including by computer telecommunications or, if computer telecommunications means have not been established by the agency, by other electronic means.** To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, ~~or staff manual or instruction,~~ **staff manual, instruction, or copies of records referred to in subparagraph (D)**. However, in each case the justification for the deletion shall be explained fully in writing**, and the extent of such deletion shall be indicated on the portion of the record which is made available or published, unless including that indication would harm an interest protected by the exemption in subsection (b) under which the deletion is made. If technically feasible, the extent of the deletion shall be indicated at the place in the record where the deletion was made.** Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of an index on request at a cost not to exceed the direct cost of duplication. **Each agency shall make the index referred to in subparagraph (E) available by computer telecommunications by December 31, 1999.** A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if--

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3)**(A)** Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon request for records which ~~(A)~~ **(i)** reasonably describes such records and ~~(B)~~ **(ii)** is made in accordance with published rules stating the time, place, fees (if

any), and procedures to be followed, shall make the records promptly available to any person.

(B) In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format. Each agency shall make reasonable efforts to maintain its records in forms or formats that are reproducible for purposes of this section.

(C) In responding under this paragraph to a request for records, an agency shall make reasonable efforts to search for the records in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information system.

(D) For purposes of this paragraph, the term "search" means to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request.

(4)(A)(i) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying the schedule of fees applicable to the processing of requests under this section and establishing procedures and guidelines for determining when such fees should be waived or reduced. Such schedule shall conform to the guidelines which shall be promulgated, pursuant to notice and receipt of public comment, by the Director of the Office of Management and Budget and which shall provide for a uniform schedule of fees for all agencies.

(ii) Such agency regulations shall provide that--

(I) fees shall be limited to reasonable standard charges for document search, duplication, and review, when records are requested for commercial use;

(II) fees shall be limited to reasonable standard charges for document duplication when records are not sought for commercial use and the request is made by an educational or noncommercial scientific institution, whose purpose is scholarly or scientific research; or a representative of the news media; and

(III) for any request not described in (I) or (II), fees shall be limited to reasonable standard charges for document search and duplication.

(iii) Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(iv) Fee schedules shall provide for the recovery of only the direct costs of search, duplication, or review. Review costs shall include only the direct costs incurred during the initial examination of a document for the purposes of determining whether the documents must be disclosed under this

section and for the purposes of withholding any portions exempt from disclosure under this section. Review costs may not include any costs incurred in resolving issues of law or policy that may be raised in the course of processing a request under this section. No fee may be charged by any agency under this section--

(I) if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee; or

(II) for any request described in clause (ii)(II) or (III) of this subparagraph for the first two hours of search time or for the first one hundred pages of duplication.

(v) No agency may require advance payment of any fee unless the requester has previously failed to pay fees in a timely fashion, or the agency has determined that the fee will exceed $250.

(vi) Nothing in this subparagraph shall supersede fees chargeable under a statute specifically providing for setting the level of fees for particular types of records.

(vii) In any action by a requester regarding the waiver of fees under this section, the court shall determine the matter de novo, provided that the court's review of the matter shall be limited to the record before the agency.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action. **In addition to any other matters to which a court accords substantial weight, a court shall accord substantial weight to an affidavit of an agency concerning the agency's determination as to technical feasibility under paragraph (2)(C) and subsection (b) and reproducibility under paragraph (3)(B).**

(C) Notwithstanding any other provision of law, the defendant shall serve an answer or otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

[~~(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.~~ Repealed by Pub. L. 98-620, Title IV, 402(2), Nov. 8, 1984, 98 Stat. 3335, 3357.]

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has

substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Special Counsel shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Special Counsel, after investigation and consideration of the evidence submitted, shall submit his findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Special Counsel recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within ~~ten days~~ **twenty days** (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

~~(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request –~~

~~(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;~~

~~(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or~~

~~(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject matter interest therein.~~

(B)(i) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days, except as provided in clause (ii) of this subparagraph.

(ii) With respect to a request for which a written notice under clause (i) extends the time limits prescribed under clause (i) of subparagraph (A), the agency shall notify the person making the request if the request cannot be processed within the time limit specified in that clause and shall provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request. Refusal by the person to reasonably modify the request or arrange such an alternative time frame shall be considered as a factor in determining whether exceptional circumstances exist for purposes of subparagraph (C).

(iii) As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular requests--

(I) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(II) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(III) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject matter interest therein.

(iv) Each agency may promulgate regulations, pursuant to notice and receipt of public comment, providing for the aggregation of certain requests by the same requestor, or by a group of requestors acting in concert, if the agency reasonably believes that such requests actually constitute a single request, which would otherwise satisfy the unusual circumstances specified in this subparagraph, and the requests involve clearly related matters. Multiple requests involving unrelated matters shall not be aggregated.

(C)**(i)** Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to

such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(ii) For purposes of this subparagraph, the term "exceptional circumstances" does not include a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

(iii) Refusal by a person to reasonably modify the scope of a request or arrange an alternative time frame for processing the request (or a modified request) under clause (ii) after being given an opportunity to do so by the agency to whom the person made the request shall be considered as a factor in determining whether exceptional circumstances exist for purposes of this subparagraph.

(D)(i) Each agency may promulgate regulations, pursuant to notice and receipt of public comment, providing for multitrack processing of requests for records based on the amount of work or time (or both) involved in processing requests.

(ii) Regulations under this subparagraph may provide a person making a request that does not qualify for the fastest multitrack processing an opportunity to limit the scope of the request in order to qualify for faster processing.

(iii) This subparagraph shall not be considered to affect the requirement under subparagraph (C) to exercise due diligence.

(E)(i) Each agency shall promulgate regulations, pursuant to notice and receipt of public comment, providing for expedited processing of requests for records--

(I) in cases in which the person requesting the records demonstrates a compelling need; and

(II) in other cases determined by the agency.

(ii) Notwithstanding clause (i), regulations under this subparagraph must ensure--

(I) that a determination of whether to provide expedited processing shall be made, and notice of the determination shall be provided to the person making the request, within 10 days after the date of the request; and

(II) expeditious consideration of administrative appeals of such determinations of whether to provide expedited processing.

(iii) An agency shall process as soon as practicable any request for records to which the agency has granted expedited processing under this subparagraph. Agency action to deny or affirm denial of a request for expedited processing pursuant to this subparagraph, and failure by an agency to respond in a timely manner to such a request shall be subject to judicial review under paragraph (4), except that the judicial review shall be based on the record before the agency at the time of the determination.

(iv) A district court of the United States shall not have jurisdiction to review an agency denial of expedited processing of a request for records after the agency has provided a complete response to the request.

(v) For purposes of this subparagraph, the term "compelling need" means--

(I) that a failure to obtain requested records on an expedited basis under this paragraph could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(II) with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.

(vi) A demonstration of a compelling need by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief.

(F) In denying a request for records, in whole or in part, an agency shall make a reasonable effort to estimate the volume of any requested matter the provision of which is denied, and shall provide any such estimate to the person making the request, unless providing such estimate would harm an interest protected by the exemption in subsection (b) pursuant to which the denial is made.

(b) This section does not apply to matters that are--

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection. **The amount of information deleted shall be indicated on the released portion of the record, unless including that indication would harm an interest protected by the exemption in this subsection under which the deletion is made. If technically feasible, the amount of the information deleted shall be indicated at the place in the record where such deletion is made.**

(c)(1) Whenever a request is made which involves access to records described in subsection (b)(7)(A) and--

(A) the investigation or proceeding involves a possible violation of criminal law; and

(B) there is reason to believe that (i) the subject of the investigation or proceeding is not aware of its pendency, and (ii) disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, the agency may, during only such time as that circumstance continues, treat the records as not subject to the requirements of this section.

(2) Whenever informant records maintained by a criminal law enforcement agency under an informant's name or personal identifier are requested by a third party according to the informant's

name or personal identifier, the agency may treat the records as not subject to the requirements of this section unless the informant's status as an informant has been officially confirmed.

(3) Whenever a request is made which involves access to records maintained by the Federal Bureau of Investigation pertaining to foreign intelligence or counterintelligence, or international terrorism, and the existence of the records is classified information as provided in subsection (b)(1), the Bureau may, as long as the existence of the records remains classified information, treat the records as not subject to the requirements of this section.

(d) This section does not authorize the withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

~~(e) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include –~~

~~(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;~~

~~(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;~~

~~(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;~~

~~(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;~~

~~(5) a copy of every rule made by such agency regarding this section;~~

~~(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and~~

~~(7) such other information as indicates efforts to administer fully this section.~~

~~The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.~~

(e)(1) On or before February 1 of each year, each agency shall submit to the Attorney General of the United States a report which shall cover the preceding fiscal year and which shall include--

(A) the number of determinations made by the agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(B)(i) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information; and

(ii) a complete list of all statutes that the agency relies upon to authorize the agency to withhold information under subsection (b)(3), a description of whether a court has upheld the decision of the agency to withhold information under each such statute, and a concise description of the scope of any information withheld;

(C) the number of requests for records pending before the agency as of September 30 of the preceding year, and the median number of days that such requests had been pending before the agency as of that date;

(D) the number of requests for records received by the agency and the number of requests which the agency processed;

(E) the median number of days taken by the agency to process different types of requests;

(F) the total amount of fees collected by the agency for processing requests; and

(G) the number of full-time staff of the agency devoted to processing requests for records under this section, and the total amount expended by the agency for processing such requests.

(2) Each agency shall make each such report available to the public including by computer telecommunications, or if computer telecommunications means have not been established by the agency, by other electronic means.

(3) The Attorney General of the United States shall make each report which has been made available by electronic means available at a single electronic access point. The Attorney General of the United States shall notify the Chairman and ranking minority member of the Committee on Government Reform and Oversight of the House of Representatives and the Chairman and ranking minority member of the Committees on Governmental Affairs and the Judiciary of the Senate, no later than April 1 of the year in which each such report is issued, that such reports are available by electronic means.

(4) The Attorney General of the United States, in consultation with the Director of the Office of Management and Budget, shall develop reporting and performance guidelines in connection with reports required by this subsection by October 1, 1997, and may establish additional requirements for such reports as the Attorney General determines may be useful.

(5) The Attorney General of the United States shall submit an annual report on or before

April 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subparagraphs (E), (F), and (G) of subsection (a)(4). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

~~(f) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any Executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.~~

(f) For purposes of this section, the term--

(1) "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency; and

(2) "record" and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this section when maintained by an agency in any format, including an electronic format.

(g) The head of each agency shall prepare and make publicly available upon request, reference material or a guide for requesting records or information from the agency, subject to the exemptions in subsection (b), including--

(1) an index of all major information systems of the agency;

(2) a description of major information and record locator systems maintained by the agency; and

(3) a handbook for obtaining various types and categories of public information from the agency pursuant to chapter 35 of title 44, and under this section.

* * * * *

Section 12. Effective Date [not to be codified].

(a) Except as provided in subsection (b), this Act shall take effect 180 days after the date of the enactment of this Act [March 31, 1997].

(b) Sections 7 and 8 shall take effect one year after the date of the enactment of this Act [October 2, 1997].

THE PRIVACY ACT OF 1974

5 U.S.C. § 552a

As Amended

§ 552a. Records maintained on individuals

(a) Definitions

For purposes of this section--

(1) the term "agency" means agency as defined in section 552(f) of this title;

(2) the term "individual" means a citizen of the United States or an alien lawfully admitted for permanent residence;

(3) the term "maintain" includes maintain, collect, use or disseminate;

(4) the term "record" means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph;

(5) the term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual;

(6) the term "statistical record" means a record in a system of records maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual, except as provided by section 8 of Title 13;

(7) the term "routine use" means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected;

(8) the term "matching program"--

(A) means any computerized comparison of--

(i) two or more automated systems of records or a system of records with non-Federal records for the purpose of--

(I) establishing or verifying the eligibility of, or continuing compliance with statutory and regulatory requirements by, applicants for, recipients or beneficiaries of, participants in, or providers of services with respect to, cash or in-kind assistance or payments under Federal benefit programs, or

(II) recouping payments or delinquent debts under such Federal benefit programs, or

(ii) two or more automated Federal personnel or payroll systems of records or a system of Federal personnel or payroll records with non-Federal records,

(B) but does not include--

(i) matches performed to produce aggregate statistical data without any personal identifiers;

(ii) matches performed to support any research or statistical project, the specific data of which may not be used to make decisions concerning the rights, benefits, or privileges of specific individuals;

(iii) matches performed, by an agency (or component thereof) which performs as its principal function any activity pertaining to the enforcement of criminal laws, subsequent to the initiation of a specific criminal or civil law enforcement investigation of a named person or persons for the purpose of gathering evidence against such person or persons;

(iv) matches of tax information (I) pursuant to section 6103(d) of the Internal Revenue Code of 1986, (II) for purposes of tax administration as defined in section 6103(b)(4) of such Code, (III) for the purpose of intercepting a tax refund due an individual under authority granted by section 464 or 1137 of the Social Security Act; or (IV) for the purpose of intercepting a tax refund due an individual under any other tax refund intercept program authorized by statute which has been determined by the Director of the Office of Management and Budget to contain verification, notice, and hearing requirements that are substantially similar to the procedures in section 1137 of the Social Security Act;

(v) matches--

(I) using records predominantly relating to Federal personnel, that are performed for routine administrative purposes (subject to guidance provided by the Director of the Office of Management and Budget pursuant to subsection (v)); or

(II) conducted by an agency using only records from systems of records maintained by that agency;

if the purpose of the match is not to take any adverse financial, personnel, disciplinary, or

other adverse action against Federal personnel; or

(vi) matches performed for foreign counterintelligence purposes or to produce background checks for security clearances of Federal personnel or Federal contractor personnel; or

(vii) Repealed. Pub.L. 104-226, § 1(b)(3)(C), Oct. 2, 1996, 110 Stat. 3033.

(9) the term "recipient agency" means any agency, or contractor thereof, receiving records contained in a system of records from a source agency for use in a matching program;

(10) the term "non-Federal agency" means any State or local government, or agency thereof, which receives records contained in a system of records from a source agency for use in a matching program;

(11) the term "source agency" means any agency which discloses records contained in a system of records to be used in a matching program, or any State or local government, or agency thereof, which discloses records to be used in a matching program;

(12) the term "Federal benefit program" means any program administered or funded by the Federal Government, or by any agent or State on behalf of the Fed real Government, providing cash or in-kind assistance in the form of payments, grants, loans, or loan guarantees to individuals; and

(13) the term "Federal personnel" means officers and employees of the Government of the United States, members of the uniformed services (including members of the Reserve Components), individuals entitled to receive immediate or deferred retirement benefits under any retirement program of the Government of the United States (including survivor benefits).

(b) Conditions of disclosure

No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record would be--

(1) to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

(2) required under section 552 of this title;

(3) for a routine use as defined in subsection (a)(7) of this section and de scribed under subsection (e)(4)(D) of this section;

(4) to the Bureau of the Census for purposes of planning or carrying out a census or survey or

related activity pursuant to the provisions of Title 13;

(5) to a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

(6) to the National Archives and Records Administration as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Archivist of the United States or the designee of the Archivist to determine whether the record has such value;

(7) to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

(8) to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of such individual;

(9) to either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

(10) to the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office;

(11) pursuant to the order of a court of competent jurisdiction; or

(12) to a consumer reporting agency in accordance with section 3711(e) of Title 31.

(c) Accounting of certain disclosures

Each agency, with respect to each system of records under its control, shall--

(1) except for disclosures made under subsections (b)(1) or (b)(2) of this section, keep an accurate accounting of--

(A) the date, nature, and purpose of each disclosure of a record to any person or to another agency made under subsection (b) of this section;

and

(B) the name and address of the person or agency to whom the disclosure is made;

(2) retain the accounting made under paragraph (1) of this subsection for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

(3) except for disclosures made under subsection (b)(7) of this section, make the accounting made under paragraph (1) of this subsection available to the individual named in the record at his request; and

(4) inform any person or other agency about any correction or notation of dispute made by the agency in accordance with subsection (d) of this section of any record that has been disclosed to the person or agency if an accounting of the disclosure was made.

(d) Access to records

Each agency that maintains a system of records shall--

(1) upon request by any individual to gain access to his record or to any information pertaining to him which is contained in the system, permit him and upon his request, a person of his own choosing to accompany him, to review the record and have a copy made of all or any portion thereof in a form comprehensible to him, except that the agency may require the individual to furnish a written statement authorizing discussion of that individual's record in the accompanying person's presence;

(2) permit the individual to request amendment of a record pertaining to him and--

(A) not later than 10 days (excluding Saturdays, Sundays, and legal public holidays) after the date of receipt of such request, acknowledge in writing such receipt; and

(B) promptly, either--

(i) make any correction of any portion thereof which the individual believes is not accurate, relevant, timely, or complete; or

(ii) inform the individual of its refusal to amend the record in accordance with his request, the reason for the refusal, the procedures established by the agency for the individual to request a review of that refusal by the head of the agency or an officer designated by the head of the agency, and the name and business address of that official;

(3) permit the individual who disagrees with the refusal of the agency to amend his record to request a review of such refusal, and not later than 30 days (excluding Saturdays, Sundays, and legal public holidays) from the date on which the individual requests such review, complete such review and make a final determination unless, for good cause shown, the head of the agency extends such 30-day period; and if, after his review, the reviewing official also refuses to amend the record in accordance with the request, permit the individual to file with

the agency a concise statement setting forth the reasons for his disagreement with the refusal of the agency, and notify the individual of the provisions for judicial review of the reviewing official's determination under subsection (g)(1)(A) of this section;

(4) in any disclosure, containing information about which the individual has filed a statement of disagreement, occurring after the filing of the statement under paragraph (3) of this subsection, clearly note any portion of the record which is disputed and provide copies of the statement and, if the agency deems it appropriate, copies of a concise statement of the reasons of the agency for not making the amendments requested, to persons or other agencies to whom the disputed record has been disclosed; and

(5) nothing in this section shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.

(e) Agency requirements

Each agency that maintains a system of records shall--

(1) maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or by Executive order of the President;

(2) collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privileges under Federal programs;

(3) inform each individual whom it asks to supply information, on the form which it uses to collect the information or on a separate form that can be retained by the individual--

(A) the authority (whether granted by statute, or by Executive order of the President) which authorizes the solicitation of the information and whether disclosure of such information is mandatory or voluntary;

(B) the principal purpose or purposes for which the information is intended to be used;

(C) the routine uses which may be made of the information, as published pursuant to paragraph (4)(D) of this subsection; and

(D) the effects on him, if any, of not providing all or any part of the requested information;

(4) subject to the provisions of paragraph (11) of this subsection, publish in the Federal Register upon establishment or revision a notice of the existence and character of the system of records, which notice shall include--

(A) the name and location of the system;

(B) the categories of individuals on whom records are maintained in the system;

(C) the categories of records maintained in the system;

(D) each routine use of the records contained in the system, including the categories of users and the purpose of such use;

(E) the policies and practices of the agency regarding storage, retrievability, access controls, retention, and disposal of the records;

(F) the title and business address of the agency official who is responsible for the system of records;

(G) the agency procedures whereby an individual can be notified at his request if the system of records contains a record pertaining to him;

(H) the agency procedures whereby an individual can be notified at his request how he can gain access to any record pertaining to him contained in the system of records, and how he can contest its content; and

(I) the categories of sources of records in the system;

(5) maintain all records which are used by the agency in making any determination about any individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination;

(6) prior to disseminating any record about an individual to any person other than an agency, unless the dissemination is made pursuant to subsection (b)(2) of this section, make reasonable efforts to assure that such records are accurate, complete, timely, and relevant for agency purposes;

(7) maintain no record describing how any individual exercises rights guaranteed by the First Amendment unless expressly authorized by statute or by the individual about whom the record is maintained or unless pertinent to and within the scope of an authorized law enforcement activity;

(8) make reasonable efforts to serve notice on an individual when any record on such individual is made available to any person under compulsory legal process when such process becomes a matter of public record;

(9) establish rules of conduct for persons involved in the design, development, operation, or maintenance of any system of records, or in maintaining any record, and instruct each such

person with respect to such rules and the requirements of this section, including any other rules and procedures adopted pursuant to this section and the penalties for noncompliance;

(10) establish appropriate administrative, technical and physical safeguards to insure the security and confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained;

(11) at least 30 days prior to publication of information under paragraph (4)(D) of this subsection, publish in the Federal Register notice of any new use or intended use of the information in the system, and provide an opportunity for interested persons to submit written data, views, or arguments to the agency; and

(12) if such agency is a recipient agency or a source agency in a matching program with a non-Federal agency, with respect to any establishment or revision of a matching program, at least 30 days prior to conducting such program, publish in the Federal Register notice of such establishment or revision.

(f) Agency rules

In order to carry out the provisions of this section, each agency that maintains a system of records shall promulgate rules, in accordance with the requirements (including general notice) of section 553 of this title, which shall--

(1) establish procedures whereby an individual can be notified in response to his request if any system of records named by the individual contains a record pertaining to him;

(2) define reasonable times, places, and requirements for identifying an individual who requests his record or information pertaining to him before the agency shall make the record or information available to the individual;

(3) establish procedures for the disclosure to an individual upon his request of his record or information pertaining to him, including special procedure, if deemed necessary, for the disclosure to an individual of medical records, including psychological records, pertaining to him;

(4) establish procedures for reviewing a request from an individual concerning the amendment of any record or information pertaining to the individual, for making a determination on the request, for an appeal within the agency of an initial adverse agency determination, and for whatever additional means may be necessary for each individual to be able to exercise fully his rights under this section; and

(5) establish fees to be charged, if any, to any individual for making copies of his record, excluding the cost of any search for and review of the record.

The Office of the Federal Register shall biennially compile and publish the rules promulgated under this subsection and agency notices published under subsection (e)(4) of this section in a form available to the public at low cost.

(g)(1) Civil remedies

Whenever any agency

(A) makes a determination under subsection (d)(3) of this section not to amend an individual's record in accordance with his request, or fails to make such review in conformity with that subsection;

(B) refuses to comply with an individual request under subsection (d)(1) of this section;

(C) fails to maintain any record concerning any individual with such accuracy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such record, and consequently a determination is made which is adverse to the individual; or

(D) fails to comply with any other provision of this section, or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual, the individual may bring a civil action against the agency, and the district courts of the United States shall have jurisdiction in the matters under the provisions of this subsection.

(2)(A) In any suit brought under the provisions of subsection (g)(1)(A) of this section, the court may order the agency to amend the individual's record in accordance with his request or in such other way as the court may direct. In such a case the court shall determine the matter de novo.

(B) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this paragraph in which the complainant has substantially prevailed.

(3)(A) In any suit brought under the provisions of subsection (g)(1)(B) of this section, the court may enjoin the agency from withholding the records and order the production to the complainant of any agency records improperly withheld from him. In such a case the court shall determine the matter de novo, and may examine the contents of any agency records in camera to determine whether the records or any portion thereof may be withheld under any of the exemptions set forth in subsection (k) of this section, and the burden is on the agency to sustain its action.

(B) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this paragraph in which the

complainant has substantially prevailed.

(4) In any suit brought under the provisions of subsection (g)(1)(C) or (D) of this section in which the court determines that the agency acted in a manner which was intentional or willful, the United States shall be liable to the individual in an amount equal to the sum of--

(A) actual damages sustained by the individual as a result of the refusal or failure, but in no case shall a person entitled to recovery receive less than the sum of $1,000; and

(B) the costs of the action together with reasonable attorney fees as determined by the court.

(5) An action to enforce any liability created under this section may be brought in the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, without regard to the amount in controversy, within two years from the date on which the cause of action a rises, except that where an agency has materially and willfully misrepresented any information required under this section to be disclosed to an individual and the information so misrepresented is material to establishment of the liability of the agency to the individual under this section, the action may be brought at any time within two years after discovery by the individual of the misrepresentation. Nothing in this section shall be construed to authorize any civil action by reason of any injury sustained as the result of a disclosure of a record prior to September 27, 1975.

(h) Rights of legal guardians

For the purposes of this section, the parent of any minor, or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction, may act on behalf of the individual.

(i)(1) Criminal penalties

Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

(2) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements of subsection (e)(4) of this section shall be guilty of a misdemeanor and fined not more than $5,000.

(3) Any person who knowingly and willfully requests or obtains any record concerning an

individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000.

(j) General exemptions

The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553(b)(1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from any part of this section except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i) if the system of records is--

(1) maintained by the Central Intelligence Agency; or

(2) maintained by an agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and the activities of prosecutors, courts, correctional, probation, pardon, or parole authorities, and which consists of (A) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (B) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (C) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

At the time rules are adopted under this subsection, the agency shall include in the statement required under section 553(c) of this title, the reasons why the system of records is to be exempted from a provision of this section.

(k) Specific exemptions

The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553(b)(1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of this section if the system of records is--

(1) subject to the provisions of section 552(b)(1) of this title;

(2) investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j)(2) of this section: Provided, however, That if any individual is denied any right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the

Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

(3) maintained in connection with providing protective services to the President of the United States or other individuals pursuant to section 3056 of Title 18;

(4) required by statute to be maintained and used solely as statistical records;

(5) investigatory material compiled solely for the purpose of determining suit ability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

(6) testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service the disclosure of which would compromise the objectivity or fairness of the testing or examination process; or

(7) evaluation material used to determine potential for promotion in the armed services, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence.

At the time rules are adopted under this subsection, the agency shall include in the statement required under section 553(c) of this title, the reasons why the system of records is to be exempted from a provision of this section.

(1)(1) Archival records

Each agency record which is accepted by the Archivist of the United States for storage, processing, and servicing in accordance with section 3103 of Title 44 shall, for the purposes of this section, be considered to be maintained by the agency which deposited the record and shall be subject to the provisions of this section. The Archivist of the United States shall not disclose the record except to the agency which maintains the record, or under rules established by that agency which are not inconsistent with the provisions of this section.

(2) Each agency record pertaining to an identifiable individual which was transferred to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, prior to the effective date of this section, shall, for the purposes of this section, be considered to be

maintained by the National Archives and shall not be subject to the provisions of this section, except that a statement generally describing such records (modeled after the requirements relating to records subject to subsections (e)(4)(A) through (G) of this section) shall be published in the Federal Register.

(3) Each agency record pertaining to an identifiable individual which is transferred to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, on or after the effective date of this section, shall, for the purposes of this section, be considered to be maintained by the National Archives and shall be exempt from the requirements of this section except subsections (e)(4)(A) through (G) and (e)(9) of this section.

(m) Government contractors

(1) When an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish an agency function, the agency shall, consistent with its authority, cause the requirements of this section to be applied to such system. For purposes of subsection (i) of this section any such contractor and any employee of such contractor, if such contract is agreed to on or after the effective date of this section, shall be considered to be an employee of an agency.

(2) A consumer reporting agency to which a record is disclosed under section 3711(e) of Title 31 shall not be considered a contractor for the purposes of this section.

(n) Mailing lists

An individual's name and address may not be sold or rented by an agency unless such action is specifically authorized by law. This provision shall not be construed to require the withholding of names and addresses otherwise permitted to be made public.

(o) Matching agreements--

(1) No record which is contained in a system of records may be disclosed to a recipient agency or non-Federal agency for use in a computer matching program except pursuant to a written agreement between the source agency and the recipient agency or non-Federal agency specifying--

(A) the purpose and legal authority for conducting the program;

(B) the justification for the program and the anticipated results, including a specific estimate of any savings;

(C) a description of the records that will be matched, including each data element that will be used, the approximate number of records that will be matched, and the projected starting

and completion dates of the matching program;

(D) procedures for providing individualized notice at the time of application, and notice periodically thereafter as directed by the Data Integrity Board of such agency (subject to guidance provided by the Director of the Office of Management and Budget pursuant to subsection (v)), to--

(i) applicants for and recipients of financial assistance or payments under Federal benefit programs, and

(ii) applicants for and holders of positions as Federal personnel,

that any information provided by such applicants, recipients, holders, and individuals may be subject to verification through matching programs;

(E) procedures for verifying information produced in such matching program as required by subsection (p);

(F) procedures for the retention and timely destruction of identifiable records created by a recipient agency or non-Federal agency in such matching program;

(G) procedures for ensuring the administrative, technical, and physical security of the records matched and the results of such programs;

(H) prohibitions on duplication and redisclosure of records provided by the source agency within or outside the recipient agency or the non-Federal agency, except where required by law or essential to the conduct of the matching program;

(I) procedures governing the use by a recipient agency or non-Federal agency of records provided in a matching program by a source agency, including procedures governing return of the records to the source agency or destruction of records used in such program;

(J) information on assessments that have been made on the accuracy of the records that will be used in such matching program; and

(K) that the Comptroller General may have access to all records of a recipient agency or a non-Federal agency that the Comptroller General deems necessary in order to monitor or verify compliance with the agreement.

(2)(A) A copy of each agreement entered into pursuant to paragraph (1) shall--

(i) be transmitted to the Committee on Governmental Affairs of the Senate and the Committee on Government Operations of the House of Representatives; and

(ii) be available upon request to the public.

(B) No such agreement shall be effective until 30 days after the date on which such a copy is transmitted pursuant to subparagraph (A)(i).

(C) Such an agreement shall remain in effect only for such period, not to exceed 18 months, as the Data Integrity Board of the agency determines is appropriate in light of the purposes, and length of time necessary for the conduct, of the matching program.

(D) Within 3 months prior to the expiration of such an agreement pursuant to subparagraph (C), the Data Integrity Board of the agency may, without additional review, renew the matching agreement for a current, ongoing matching program for not more than one additional year if--

(i) such program will be conducted without any change; and

(ii) each party to the agreement certifies to the Board in writing that the program has been conducted in compliance with the agreement.

(p) Verification and opportunity to contest findings

(1) In order to protect any individual whose records are used in a matching program, no recipient agency, non-Federal agency, or source agency may suspend, terminate, reduce, or make a final denial of any financial assistance or payment under a Federal benefit program to such individual, or take other adverse action against such individual, as a result of information produced by such matching program, until--

(A)(i) the agency has independently verified the information; or

(ii) the Data Integrity Board of the agency, or in the case of a non-Federal agency the Data Integrity Board of the source agency, determines in accordance with guidance issued by the Director of the Office of Management and Budget that--

(I) the information is limited to identification and amount of benefits paid by the source agency under a Federal benefit program; and

(II) there is a high degree of confidence that the information provided to the recipient agency is accurate;

(B) the individual receives a notice from the agency containing a statement of its findings and informing the individual of the opportunity to contest such findings; and

(C)(i) the expiration of any time period established for the program by statute or

regulation for the individual to respond to that notice; or

(ii) in the case of a program for which no such period is established, the end of the 30-day period beginning on the date on which notice under subparagraph (B) is mailed or otherwise provided to the individual.

(2) Independent verification referred to in paragraph (1) requires investigation and confirmation of specific information relating to an individual that is used as a basis for an adverse action against the individual, including where applicable investigation and confirmation of--

(A) the amount of any asset or income involved;

(B) whether such individual actually has or had access to such asset or income for such individual's own use; and

(C) the period or periods when the individual actually had such asset or income.

(3) Notwithstanding paragraph (1), an agency may take any appropriate action otherwise prohibited by such paragraph if the agency determines that the public health or public safety may be adversely affected or significantly threatened during any notice period required by such paragraph.

(q) Sanctions

(1) Notwithstanding any other provision of law, no source agency may disclose any record which is contained in a system of records to a recipient agency or non-Federal agency for a matching program if such source agency has reason to believe that the requirements of subsection (p), or any matching agreement entered into pursuant to subsection (o), or both, are not being met by such recipient agency.

(2) No source agency may renew a matching agreement unless--

(A) the recipient agency or non-Federal agency has certified that it has complied with the provisions of that agreement; and

(B) the source agency has no reason to believe that the certification is inaccurate.

(r) Report on new systems and matching programs

Each agency that proposes to establish or make a significant change in a system of records or a matching program shall provide adequate advance notice of any such proposal (in duplicate) to the Committee on Government Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and

Budget in order to permit an evaluation of the probable or potential effect of such proposal on the privacy or other rights of individuals.

(s) Biennial report

The President shall biennially submit to the Speaker of the House of Representatives and the President pro tempore of the Senate a report--

(1) describing the actions of the Director of the Office of Management and Budget pursuant to section 6 of the Privacy Act of 1974 during the preceding two years;

(2) describing the exercise of individual rights of access and amendment under this section during such years;

(3) identifying changes in or additions to systems of records;

(4) containing such other information concerning administration of this section as may be necessary or useful to the Congress in reviewing the effectiveness of this section in carrying out the purposes of the Privacy Act of 1974.

(t) Effect of other laws

(1) No agency shall rely on any exemption contained in section 552 of this title to withhold from an individual any record which is otherwise accessible to such individual under the provisions of this section.

(2) No agency shall rely on any exemption in this section to withhold from an individual any record which is otherwise accessible to such individual under the provisions of section 552 of this title.

(u) Data Integrity Boards

(1) Every agency conducting or participating in a matching program shall establish a Data Integrity Board to oversee and coordinate among the various com pennants of such agency the agency's implementation of this section.

(2) Each Data Integrity Board shall consist of senior officials designated by the head of the agency, and shall include any senior official designated by the head of the agency as responsible for implementation of this section, and the inspector general of the agency, if any. The inspector general shall not serve as chairman of the Data Integrity Board.

(3) Each Data Integrity Board--

(A) shall review, approve, and maintain all written agreements for receipt or disclosure of agency records for matching programs to ensure compliance with subsection (o), and all relevant statutes, regulations, and guidelines;

(B) shall review all matching programs in which the agency has participated during the year, either as a source agency or recipient agency, determine compliance with applicable laws, regulations, guidelines, and agency agreements, and assess the costs and benefits of such programs;

(C) shall review all recurring matching programs in which the agency has participated during the year, either as a source agency or recipient agency, for continued justification for such disclosures;

(D) shall compile an annual report, which shall be submitted to the head of the agency and the Office of Management and Budget and made available to the public on request, describing the matching activities of the agency, including--

(i) matching programs in which the agency has participated as a source agency or recipient agency;

(ii) matching agreements proposed under subsection (o) that were disapproved by the Board;

(iii) any changes in membership or structure of the Board in the preceding year;

(iv) the reasons for any waiver of the requirement in paragraph (4) of this section for completion and submission of a cost-benefit analysis prior to the approval of a matching program;

(v) any violations of matching agreements that have been alleged or identified and any corrective action taken; and

(vi) any other information required by the Director of the Office of Management and Budget to be included in such report;

(E) shall serve as a clearinghouse for receiving and providing information on the accuracy, completeness, and reliability of records used in matching programs;

(F) shall provide interpretation and guidance to agency components and personnel on the requirements of this section for matching programs;

(G) shall review agency recordkeeping and disposal policies and practices for matching programs to assure compliance with this section; and

(H) may review and report on any agency matching activities that are not matching programs.

(4)(A) Except as provided in subparagraphs (B) and (C), a Data Integrity Board shall not approve any written agreement for a matching program unless the agency has completed and submitted to such Board a cost-benefit analysis of the proposed program and such analysis demonstrates that the program is likely to be cost effective.

(B) The Board may waive the requirements of subparagraph (A) of this paragraph if it determines in writing, in accordance with guidelines prescribed by the Director of the Office of Management and Budget, that a cost-benefit analysis is not required.

(C) A cost-benefit analysis shall not be required under subparagraph (A) prior to the initial approval of a written agreement for a matching program that is specifically required by statute. Any subsequent written agreement for such a program shall not be approved by the Data Integrity Board unless the agency has submitted a cost-benefit analysis of the program as conducted under the preceding approval of such agreement.

(5)(A) If a matching agreement is disapproved by a Data Integrity Board, any party to such agreement may appeal the disapproval to the Director of the Office of Management and Budget. Timely notice of the filing of such an appeal shall be provided by the Director of the Office of Management and Budget to the Committee on Governmental Affairs of the Senate and the Committee on Government Operations of the House of Representatives.

(B) The Director of the Office of Management and Budget may approve a matching agreement notwithstanding the disapproval of a Data Integrity Board if the Director determines that--

(i) the matching program will be consistent with all applicable legal, regulatory, and policy requirements;

(ii) there is adequate evidence that the matching agreement will be cost-effective; and

(iii) the matching program is in the public interest.

(C) The decision of the Director to approve a matching agreement shall not take effect until 30 days after it is reported to committees described in subparagraph (A).

(D) If the Data Integrity Board and the Director of the Office of Management and Budget disapprove a matching program proposed by the inspector general of an agency, the inspector general may report the disapproval to the head of the agency and to the Congress.

(6) The Director of the Office of Management and Budget shall, annually during the first 3 years after the date of enactment of this subsection and biennially thereafter, consolidate in a report to the Congress the information contained in the reports from the various Data Integrity Boards under paragraph (3)(D). Such report shall include detailed information

about costs and benefits of matching programs that are conducted during the period covered by such consolidated report, and shall identify each waiver granted by a Data Integrity Board of the requirement for completion and submission of a cost-benefit analysis and the reasons for granting the waiver.

(7) In the reports required by paragraphs (3)(D) and (6), agency matching activities that are not matching programs may be reported on an aggregate basis, if and to the extent necessary to protect ongoing law enforcement or counterintelligence investigations.

(v) Office of Management and Budget responsibilities

The Director of the Office of Management and Budget shall--

(1) develop and, after notice and opportunity for public comment, prescribe guidelines and regulations for the use of agencies in implementing the provisions of this section; and

(2) provide continuing assistance to and oversight of the implementation of this section by agencies.

The following section was enacted as part of the Privacy Act, but was not codified; it may be found at § 552a (note).

Sec. 7 (a)(1) It shall be unlawful for any Federal, State or local government agency to deny to any individual any right, benefit, or privilege provided by law because of such individual's refusal to disclose his social security account number.

(2) the provisions of paragraph (1) of this subsection shall not apply with respect to--

(A) any disclosure which is required by Federal statute, or

(B) any disclosure of a social security number to any Federal, State, or local agency maintaining a system of records in existence and operating before January 1, 1975, if such disclosure was required under statute or regulation adopted prior to such date to verify the identity of an individual.

(b) Any Federal, State or local government agency which requests an individual to disclose his social security account number shall inform that individual whether that disclosure is mandatory or voluntary, by what statutory or other authority such number is solicited, and what uses will be made of it.

The following sections were enacted as part of Pub.L. 100-503, the Computer Matching and Privacy Protection Act of 1988; they may be found at § 552a (note).

Sec. 6 Functions of the Director of the Office of Management and Budget.

(b) Implementation Guidance for Amendments-- The Director shall, pursuant to section 552a(v) of Title 5, United States Code, develop guidelines and regulations for the use of agencies in implementing the amendments made by this Act not later than 8 months after the date of enactment of this Act.

Sec. 9 Rules of Construction.

Nothing in the amendments made by this Act shall be construed to authorize--

(1) the establishment or maintenance by any agency of a national data bank that combines, merges, or links information on individuals maintained in systems of records by other Federal agencies;

(2) the direct linking of computerized systems of records maintained by Federal agencies;

(3) the computer matching of records not otherwise authorized by law; or

(4) the disclosure of records for computer matching, except to a Federal, State, or local agency.

Sec. 10 Effective Dates.

(a) In General-- Except as provided in subsection (b), the amendments made by this Act shall take effect 9 months after the date of enactment of this Act.

(b) Exceptions-- The amendment made by sections 3(b) [Notice of Matching Programs - Report to Congress and the Office of Management and Budget], 6 [Functions of the Director of the Office of Management and Budget], 7 [Compilation of Rules and Notices] and 8 [Annual Report] of this Act shall take effect upon enactment.

	Cost	Order Through
Approved Prescription Drug Products w/Therapeutic Equivalence Evaluations		*GPO*
Biopharmaceutics Guidances (Microfiche)	*.50 ea.*	*FDA/FOI*
Bio-Research Monitoring Manual for Supervisory Investigators, NCTR Nonclinical *(One-week course conducted by the National Center for Toxicological Research)*	*38.50*	*FDA/FOI*
Center for Veterinary Medicine Policy and Procedures Manual *(Primarily concerned with the preparation and review of documents within the Center for Veterinary Medicine)*	*51.20*	*FDA/FOI*
DDLC - Rx Drug Study Bulletin	*.10 per pg.*	*FDA/FOI*
Debarment List	*.10 per pg.*	*FDA/FOI*
DESI - Generic Names Vol. II - Active Ingredient List - October 1968 *(Printout)*	*68.00*	*FDA/FOI*
Drug GMP	*.10 per pg.*	*FDA/FOI*
Drug Approval Letters	*.10 per pg.*	*FDA/FOI*
Drug Autoanalysis Manual *(Provides assurance of homogeneity within a single lot for a safe drug supply. Specifications are for all table monographs where the active ingredient is present in quantities*	*56.00*	*FDA/FOI*

usually 50 mg. or less)		
Drug Master File List (microfiche)	*.50 ea.*	*FDA/FOI*
Enforcement Reports		*GPO*
FDA Location Directory	*11.00*	*GPO*
Field Management Directives *(FDA Field policy in the areas of operations management, planning and budget, program , management)*	*33.80*	*FDA/FOI*
510Ks - See Premarket Notifications	*.50 ea.*	*FDA/FOI*
FOI Daily Log	*5.00 per printout* *25.00/wk on diskette*	*FDA/FOI*
Inactive Ingredient (Hardcopy)	*.10 per pg*	*FDA/FOI*
Ineligible Investigators to Receive Investigational Products	*.10 per pg.*	*FDA/FOI*
Inspector's Technical Guide *(Technical information for FDA inspectors, not previously available on a broad scale)*	*20.30*	*FDA/FOI*
Inspector's Training Manual *(Basic training manual for food and drug inspectors and inspection techniques)*	*22.30*	*FDA/FOI*
List of Premarketed Notifications (510ks) *(These 510Ks have previously been made available to the public and are available on microfiche only. The list by number only)*	*.10 per pg*	*FDA/FOI*

Lists of Summary Basis for Approvals (SBA's), Reviews and Final Printed Labeling (FPL) *(These lists are by NDA and ANDA number, generic name, trade name and sponsor. These SBAs, Reviews, and FPL have previously been made available to the public and are currently available on microfiche only.)*	*.10 per pg.*	*FDA/FOI*
Manufacturing and Controls Handbook	*26.20*	*FDA/FOI*
Memorandum of Understanding between FDA and State Agencies *(Chapter 3 of the Investigation Operations Manual)*		
OTC Drug Review Ingredient Status Report	*6.80*	*FDA/FOI*
Post '62 Product Printout	*85.00*	*FDA/FOI*
Premarket Notification (510Ks), Listing by Manufacturer, Product, Panel, Control and Log Out Date.	*.50 ea.*	*FDA/FOI*
Quarterly Activities Report, FDA *(Through 1995)*	*.10 per pg.*	*FDA/FOI*
Regulatory Letters (Warning Letters) *(New Title as of May 1991), Warning Letters)*	*.10 per pg* *.50 microfiche*	*FDA/FOI*
Staff Manual Guides, FDA (4 Vols.) *(Directives issued by FDA to establish policy, organization, procedures or responsibilities in the administration area)*	*319.00*	*FDA/FOI*
Summary Basis of Approval (microfiche)	*.50 ea.*	*FDA/FOI*
Warning Letters *(June 1991 to present)*	*.10 per pg.*	*FDA/FOI*

AOAC *AOAC*
481 North Frederick Avenue Suite 500
Gaithersburg, MD 20877
Telephone (301) 924-7077

GPO *Superintendent of Documents*
Government Printing Office
Washington, DC 20402
Telephone (202) 512-1530
Web Site:
HTTP://WWW.ACCESS.GPO.GOV/SU_DOCS

FDA/FOI *Food and Drug Administration*
Freedom of Information Staff, HFI-35
Rockville, MD 20857
Telephone (301) 827-6500

Materials listed above may be viewed in FDA's Freedom of Information Public Room which is open Monday through Friday from 9:00 a.m. to 4:00 p.m. The Public Room is located at 5600 Fishers Lane, Room 12A-30, Rockville, MD 20857. For further information call (301) 827-6500.

	NTIS ORDER NO.	PAPER COPY*	MICRO-FICHE*
Analyst Operation Manual (Training information, instructions and procedures for new laboratory personnel).	PB85-211639	$87.00 each	$11.50 each
AIDS Vaccine Workshop (3 Vols.)	PB87-177317	50.00	9.00
Compliance Policy Guide (7132.16)	PB92-147362	12.50	
Compliance Policy Guides (Statements of FDA Compliance Policy, including those statements which contain regulatory action guidance info.)			
Basic Manual	PB95-915499	61.00	6.00 (Handling)
Subscription	PB94-915400	*Special	Handling
Compliance Program Guidance Manual (Programs, plans and instructions directed to FDA field operations for Program Management Systems (PMS) project implementation)			
Food and Cosmetics - Section I			
Basic Manual	PB94-920599	91.00	
Subscription	PB94-920500	255.50	
Drugs and Biologics - Section II			
Basic Manual	PB94-920699	105.00	
Subscription	PB94-920600	250.00	
Veterinary Medicine - Section III			
Basic Manual	PB94-920899	44.50	

Subscription	*PB94-920800*	*140.00*	
Medical and Radiological Devices - Section IV			
Basic Manual	*PB94-920999*	*84.00*	
Subscription	*PB94-920900*	*210.00*	
Costart Dictionary	*PB90-189784*	*50.00*	*9.00*
Drug and Device Product Approval List	*PB94-923700*	**Special Handling*	
FDA Almanac FY 1994	*PB95-147765*	*19.50*	*9.00*
FDA Certified Mammography Facilities Listing	*SUB-5386*	*195.00*	*~~Diskettes~~* ***(4)***
	SUB-5386 (One Diskette $ 5.00) *(Price Code is D01)*		
NAS/NRS Reviewed Prescription Drugs			
Good Laboratories Practices Manual	*PB82-180779*	*47.00*	*11.50*
Guide to Inspection of Computerized Systems in Drug Processing	*PB84-189588*	*22.00*	*11.50*
Import Alerts			
Package	*PB93-924599*	*85.00*	
Subscription	*PB94-924500*	**Special Handling*	
Investigations Operations Manual *(Standard operating inspectional and investigational procedures and instructions used by FDA investigational personnel)*			
Basic Manual	*PB94-913399*	*61.00*	
Subscription Service	*PB93-913300*	**Special Handling*	
Medical Device Report (MDR) from the			

Device Experience Network (DEN)

Subscription	*PB90-920300*	**Special Handling*	
	NTIS ORDER NO.	***PAPER COPY***	***MICRO-FICHE****

Monthly Import Detention List

Single copy		
Subscription	*PB94-923600*	**Special Handling*

Pesticides Analytical Manual
(Procedures and methods used in FDA laboratories for surveillance of the extent and significance of contamination of man and his environment by pesticides and their metabolites)

Volume I

Basic Manual	*PB92-911899*	*105.00*
Standing order	*PB94-911800*	**Special Handling*

Volume II

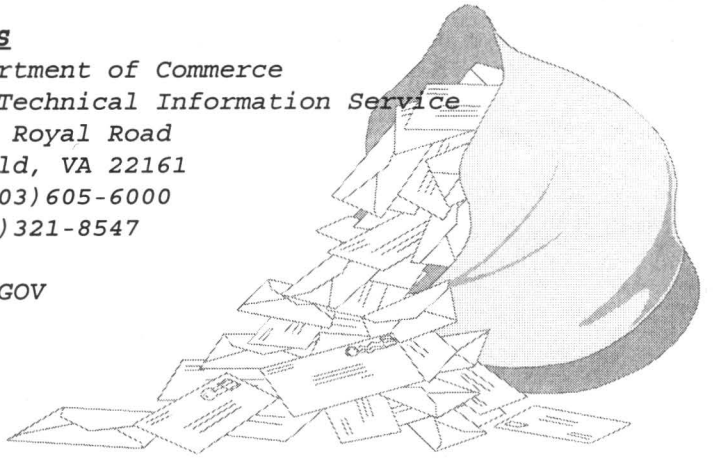
Basic Manual	*PB92-911999*	*224.00*
Standing order	*PB94-911900*	**Special Handling*

Policy and Guidance Handbook for FDA Advisory Committee	*PB94-158854*	*40.00*	
Recall Procedures, chapter 5-00 of the Regulatory Procedures Manual	*PB88-218128*	*26.00*	*11.50*
Saccharin Report #1	*PB-292695*	*47.00*	*11.50*
Saccharin Report #2	*PB-292069*	*87.00*	*11.50*

	PAPER NTIS ORDER NO.	MICRO-COPY*	FICHE*
Regulatory Procedures Manual *(Guidance on regulatory policy and support processing procedures)*	PB95-265534	52.00	
Vaccines Adverse Events Reporting System July 1, 1990 - October 31, 1990	PB92-141225 PB92-501410		9.00 90.00(Diskette)
Vaccines Adverse Events Reporting System November 1, 1990 and Thereafter	PB92-914801 PB92-592281		30.00 90.00(Diskette)
Vaccines Adverse Events Reporting System November 1, 1990 and Thereafter	PB92-914801 PB92-592281		30.00 90.00(Diskette)
Vaccines Adverse Events Reporting System One-Year Subscription	PB92-914800 PB92-592280		252.00 1080.00(Diskette)

**Prices listed were accurate in January 1995, applicable in North America only. However, for current prices for domestic as well as foreign customers please contact NTIS for quotations and/or further assistance.*

NTIS
U.S. Department of Commerce
National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Phone: (703)605-6000
Fax: (703)321-8547
Web Site:
WWW.NTIS.GOV



HEADQUARTERS COMPONENT FREEDOM OF INFORMATION/PRIVACY ACT OFFICERS AND CONTACTS

November 1998

FREEDOM OF INFORMATION STAFF (HFI-35)
Parklawn Bldg., Room 12A-16
Telephone (301) 827-6500
Fax (301) 443-1726
Confirm Fax Received (301) 443-2414
Betty B. Dorsey, Director
Les Weinstein, Deputy Director/Denials & Appeals Officer
Barbara Schulman, Supervisor
Walter Marshall, Supervisor

COMPONENT OFFICE		OFFICERS AND CONTACTS*	FOI STAFF (HFI-35) LIAISONS
GCF-1	Office of Chief Counsel (827-1137) Pkln, Room 6-57 (Fax 827-3054)	June Stephenson	Theola Myo Khin
HF-3	Office of Administrative Law Judge (827-7120) Room 9-57	Margaret Smith	Mayo Nava
HF-5	Special Assistant for Investigations (443-5742) Pkln, Room 15-44	Brian Somers	Mayo Nava
HF-7	Chief Mediator and Ombudsman (827-3390) Pkln, Room 14-105	Tracey Forfa	Mayo Nava
HF-8	Office of Women's Health (827-0350) Pkln, Room 15-61	Kennerly Chapman	Mayo Nava
HF-9	Office of Internal Affairs (827-0243)Church Bldg., Rm. 700	Lou Caputo	Mayo Nava
HF-12	Office of Special Health Issues (827-4460) Pkln, Room 9-49	Donald Pohl	Mayo Nava
HF-15	Equal Employment Opportunity and Civil Rights Office (827-4840) Pkln, Room 8-72	Lena Clark Jean Bogle	Mayo Nava

COMPONENT OFFICE		OFFICERS AND CONTACTS*	FOI STAFF (HFI-35) LIAISONS
HF-22	Deputy Commissioner for Policy (827-0565) Pkln, Room 14-101	Lisa Barclay	Mayo Nava
HF-28	Deputy Commissioner for Operations (827-3320) Pkln, Room 14-71	Randy Wykoff	Mayo Nava
HF-32	Office of Science (827-3038) Pkln, Room 17-35	Donna Mentch	Mayo Nava
HF-35	Office of Orphan Products Development (827-0983) Pkln, Room 8-73 (Fax 443-4915)	Lisa Hubbard	Mary Sejas
HF-40	Commissioner's Office (827-4435) Pkln, Room 16-70 (Fax 443-1863)	Anne Crawford Vicky Wolfhard	Mayo Nava
HF-60	Office of External Affairs (827-3364) Pkln, Room 14C-03	Mary Gross	Mayo Nava
HFA-4	Deputy Commissioner for Management and Systems (827-3389) Pkln, Room 14-82	Nancy Ross West	Theola Myo Khin
HFA-80	Office of Information Resources Management (827-4655) Pkln, Room 16B-30	Charlie Schramm	Theola Myo Khin
HFA-100	Office of Financial Management (827-5004) Pkln, Room 11-61	Fran Graybill	Theola Myo Khin
HFA-200	Facilities & Central Services (827-7027) Room N-135, MPN2	Felton Armstrong	Theola Myo khin
HFA-250	Information Collection & Dissemination Branch (827-3158) Pkln, Room 16B-19	Seung Ja Sinatra	Theola Myo Khin
HFA-300	Division of Management Systems & Policy (827-5503) Pkln, Room 4-72	Gail Kohlhorst Anita Prout	Theola Myo Khin

COMPONENT OFFICE		OFFICERS AND CONTACTS*	FOI STAFF (HFI-35) LIAISONS
HFA-305	Dockets Management Branch (827-6860) (Fax 827-6870) 5630 Fishers Ln., Room 1061	Jennie Butler Gloria Ortega*	Charles Tobin
HFA-306	Committee Management (FDA Advisory Committee) (827-5496) Pkln, Rm. 4B-17 (Fax 827-5891)	Donna Combs	Peggy Linton
HFA-340	Organization Planning Branch (827-4812) Pkln, Room 4-72	Paul Jones	Theola Myo Khin
HFA-400	Office of Human Resources Management (827-4810) Pkln, Bldg., Room 4B-03	Delores Willis	Theola Myo Khin
HFA-500	Office of Contracts and Grants (827-6890) 5630 Fishers Ln., Rm. 2035 (Fax 827-7029)	Beatrice Droke Tracey O'Neill*	Theola Myo Khin
HFC-230	Office of Regulatory Affairs (827-0420) Twinbrook Bldg. 5 Ste 517 (Fax 827-0482)	Sharon Sheehan Terry Roseby*	Mary Sejas
HFC-300	Office of Criminal Investigations (9-301-294-4052) MPN #2 Room 250	Dwight Rawls	Mary Sejas
HFD-205	Center for Drug Evaluation and Research (827-4565 or 827-4583) Pkln Room 12B-05 (Fax 827-4576)	Carolann Hooton JoAnna Riggs*	Mary Sejas
HFE-50	Associate Commissioner for Consumer Affairs (827-4396) Pkln, Room 16-75	Phyllis Weller	Theola Myo Khin
HFG-1	Office of International Affairs (827-4480) Pkln, Room 15A-16	Merton Smith	Mayo Nava

COMPONENT OFFICE		OFFICERS AND CONTACTS*	FOI STAFF (HFI-35) LIAISONS
HFI-20	Associate Commissioner for Public Affairs (827-6242) Pkln, Room 15-05	Cecelia Norwood	Mayo Nava
HFM-48	Center for Biologics Evaluation and Research (827-2000) (Fax 827-3843) Rockwall Bldg. Room 615	Fred Sadler Debbie Taub	Claire Brodsky
HFP-1	Associate Commissioner for Planning and Evaluation (827-5297) Pkln, Room 10-61 (Fax 827-5298)	Susan Massey	Theola Myo Khin
HFS-22	Center for Food Safety and Applied Nutrition (202 205-5309) (Fax 202 205-4970) FB8 Room 6848	Patricia Gee Michael Howard*	Mary Hodge
HFT-325	National Center for Toxicological Research (870 543-7130) (Fax 870 543-7576) Jefferson, Arkansas 72079	Victor Attwood	Mayo Nava
HFV-12	Center for Veterinary Medicine (827-6510) MPN Bldg. #2, Rm 400 (Fax 594-1831)	Marilyn Broderick	Peggy Linton
HFW-1	Associate Commissioner for Legislative Affairs (827-0099) Pkln, Room 15-55 (Fax 443-2567)	Maggie Bierwirth	Theola Myo Khin
HFY-12	Associate Commissioner for Health Affairs (827-6599) Pkln, Room 15-26	Jane Peterson	Mayo Nava
HFZ-82	Center for Devices and Radiological Health (594-4774 x128)Oak Grove Bldg. 4 (Fax 594-4792) Rm. 108	Ann Curtsinger Sandy McGeehan*	Jeri Colmes

DISTRICT FREEDOM OF INFORMATION/ PRIVACY ACT OFFICERS AND CONTACTS

November 1998

DISTRICT OFFICE	OFFICERS AND CONTACTS*	TELEPHONE	FOI STAFF (HFI-35) LIAISONS
ATLANTA DISTRICT (HFR-SE140) 60 Eighth Street, N.E. Atlanta, Georgia 30309 Fax Number: (404) 347-4604	Philip S. Campbell Renee Johnson*	(404) 347-4001 x5236 (404) 347-4001 x5234	Lisa Latimer
BALTIMORE DISTRICT (HFR-MA240) 900 Madison Avenue Baltimore, Maryland 21201 Fax Number: (410) 962-2219	Wiley Williamson, III Patty Simmons*	(410) 962-4366 x136 (410) 962-4099 x130	Lisa Latimer
BUFFALO DISTRICT (HFR-NE340) 599 Delaware Avenue Buffalo, New York 14202 Fax Number: (716) 551-4499	Shelly Salzman	(716) 551-4461 x3177	Wade E. White
CHICAGO DISTRICT (HFR-MW140) 300 S. Riverside Plaza, Suite 550 Chicago, Illinois 60606 Fax Number: (312) 353-0947	Richard Harrison Edna Porter	(312) 353-5863 x163 (312) 353-5863 x172	Wade E. White
CINCINNATI DISTRICT (HFR-MA440) 6751 Steger Dr Cincinnati, Ohio 45237-3097 Fax Number: (513) 679-2773/2774	Eric E. Batchelor Jackie Prather	(513) 679-2700 x161 (513) 679-2700 x169	Lisa Latimer
DALLAS DISTRICT (HFR-SW140) 3310 Live Oak Street Dallas, Texas 75204 Fax Number: (214) 655-5331	Elaine Crosby Patrick Kaelin*	(214) 655-5317 x161 (214) 655-5317 x309	Lisa Latimer

DISTRICT OFFICE	OFFICERS AND CONTACTS*	TELEPHONE	FOI STAFF (HFI-35) LIAISONS
DENVER DISTRICT (HFR-SW240) P.O. Box 25087 DFC Building 20 West 6th Avenue & Kipling Street Denver, Colorado 80225-0087 Fax Number: (303) 236-3551	H. Thomas Warwick Sylvia Watson*	(303) 236-3054 (303) 236-3042	Wade E. White
DETROIT DISTRICT (HFR-MW240) 1560 E. Jefferson Avenue Detroit, Michigan 48207 Fax Number: (313) 226-3076	Gay Dries	(313) 226-6260 x167	Shera Behram
FLORIDA DISTRICT (HFR-SE240) 555 Winderley Pl., Ste 200 Maitland, Florida 32751 Fax Number: (407)475-4769	Edward R. Atkins Miriam Jones*	(407) 475-4734 (407) 475-4733 (407) 475-4700 (Main number)	Rochelle Coleman
KANSAS CITY DISTRICT (HFR-SW340) 11510 W. 80th Street P.O. Box 15905 Lenexa, Kansas 66285 Fax Number: (913) 752-2111	Rich Pendleton Renita Boyd*	(913) 752-2103 (913) 752-2104	Wade E. White
LOS ANGELES DISTRICT (HFR-P240) 19900 MacArthur Boulevard, Suite 300 Irvine, California 92612	Robert W. Nichol Frank Mendoza* Sandra Williams* Steve Condrey	(949) 798-7667 (949) 798-7749 (949) 798-7666 (949) 798-7640	Rochelle Coleman
MINNEAPOLIS DISTRICT (HFR-MW340) 240 Hennepin Avenue Minneapolis, Minnesota 55401 Fax Number: (612) 334-4142	Ed Dee Becky Kimball*	(612) 334-4114 x154 (612) 334-4100 x155	Lisa Latimer

DISTRICT OFFICE	OFFICERS AND CONTACTS*	TELEPHONE	FOI STAFF (HFI-35) LIAISONS
NASHVILLE DISTRICT (HFR-SE340) 297 Plus Park Boulevard Nashville, Tennessee 37217 Fax Number: (615) 781-5383	Frank J. Jancarek Joseph Hayes* Howard Lewis* Kathy Lyle*	(615) 781-5390 x126 (615) 781-5389 x125 (615) 781-5388 x124 (615) 781-5390 x126	Lisa Latimer
NEW ENGLAND (HFR-NE240) One Montvale Avenue Stoneham, Massachusetts 02180-3542 Fax Numbers: FOIA (781) 279-1738 Privacy (781) 279-1742	Gail Costello Barbara Recupero* Jim O'Neill (backup)* Linda Muccioli/Privacy	(781) 279-1675 x178 (781) 279-1675 x179 (781) 279-1675 x161 (781) 279-1675 x114	Shera Behram
NEW JERSEY DISTRICT (HFR-MA340) Waterview Corporate Center 10 Waterview Boulevard, 3rd Floor Parsippany, New Jersey 07054 Fax Number: (973) 526-6069	Ray Abrahams Louise Miranda	(973) 526-6002 (973) 526-6003	Wade E. White
NEW ORLEANS DISTRICT (HFR-SE440) 4298 Elysian Fields Avenue New Orleans, Louisiana 70122-3848 Fax Number: (504) 589-4657	Richard Debo Karen Relayson*	(504) 589-7166 x172 (504) 589-7166 x131	Lisa Latimer
NEW YORK DISTRICT (HFR-NE140) 850 Third Avenue Brooklyn, New York 11232 Fax Number: (718) 340-7011	Lillian Aveta Ella Almodovar	(718) 340-7000 x5142 (718) 340-7000 x5535	Lisa Latimer
PHILADELPHIA DISTRICT (HFR-MA140) U.S. Customhouse 2nd and Chestnut Streets, Room 900 Philadelphia, Pennsylvania 19106 Fax Number: (215) 597-8212	Charles Thorne Robin Rivers*	(215) 597-4390 x4410 (215) 597-4300 x4405	Lisa Latimer

DISTRICT OFFICE	OFFICERS AND CONTACTS*	TELEPHONE	FOI STAFF (HFI-35) LIAISONS
SAN FRANCISCO DISTRICT (HFR-PA140) 1431 Harbor Bay Parkway Alameda, California 94502-7070 Fax Number: (510) 337-6703	Steve Kendall Linda Irwin*	(510) 337-6820 (510) 337-6813x1037	Wade E. White
SAN JUAN DISTRICT (HFR-SE540) 466 Fernandez Juncos Avenue Puerto de Tierra San Juan, Puerto Rico 00901-3223 Fax Number: (809) 729-6658	Mary Mason	(787) 729-6894 x7	Lisa Latimer
SEATTLE DISTRICT (HFR-P340) P.O. Box 3012 Bothell, Washington 98041-3012 Fax Number: (425) 483-4760	Celeste Corcoran Stephanie Dalgliesh*	(425) 483 4971 (425) 483-4948	Wade E. White
ST. LOUIS BRANCH (HFR-SW440) 12 Sunnen Drive, Suite 122 St. Louis, Missouri 63143 Fax Number: (314) 645-2969	Spencer Sorenson Sue Petru*	(314) 645-1167 x150 (314) 645-1167 x152	Wade E. White

Useful Internet and Intranet sites and Web pages

Staff Manual Guide 2460.7
Procedures for Implementing The Freedom of Information (FOI) Act
http://ease.fda.gov/learnfda/manuals/smg/smg-htm/24607.htm

Information and Records from Food and Drug Administration (Includes how to make a request and a fee schedule) **http://www.fda.gov/opacom/backgrounders/foiahand.html**

Index of Food and Drug Administration Electronic Reading Room Documents
http://www.fda.gov/foi/electrr.htm

How to make a FOIA request
http://www.fda.gov/opacom/backgrounders/foiahand.html

U.S. Department of Justice Home Page, Freedom of Information
http://www.usdoj.gov/foia/index.html

U. S. Department of Justice Freedom of Information Act Reference Materials
http://www.usdoj.gov/foia/04_7.html

U. S. Department of Justice Freedom of Information Act Reference Guide
Revised December 1998
http://www.usdoj.gov/04foia/04_3.html

SECTION VI

INDEXES

Section VI

Indexes

In Section VI This section contains the following indexes.

INDEX TO 1974 AND 1977 PUBLIC INFORMATION REGULATIONS

(1974 Preamble Citations are in Parentheses)
[1977 Preamble Citations are in Brackets]

KEY WORDS FROM SECTION III
ANSWERS TO FREQUENTLY ASKED QUESTIONS

☆U.S. GOVERNMENT PRINTING OFFICE:1999-718-488/93657

DIVISION OF COMPLIANCE POLICY
OFFICE OF ENFORCEMENT
OFFICE OF REGULATORY AFFAIRS
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES