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Description of document: **Department of Health & Human Services (DHHS)
Information Quality End-of-Year Reports for
FY2005 - FY2007**

Requested date: 28-September-2008

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Titles of documents: HHS Fiscal Year 2005 Information Quality Report
2006 Year-End Information Quality Report
2007 Year-End Information Quality Report

Source of document: Department of Health and Human Services FOIA Office
Freedom of Information Officer
Mary E. Switzer Building, Room 2221
330 C Street, S.W.
Washington, DC 20201
Fax: 202-690-8320
[Online FOIA Form](#)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

Case No. 2009-0023GD

December 16, 2010

This is in response to your September 28, 2008, Freedom of Information Act (FOIA) request for records pertaining to HHS Information Quality End-of-Year Report for FY2005, FY2006, and FY2007.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) located 56 pages of record responsive to your request, which are enclosed in their entirety.

Sincerely,

A handwritten signature in black ink, which appears to read "Robert Eckert for". The signature is written in a cursive style.

Robert Eckert
Director
FOI/Privacy Acts Division
Office of Public Affairs

HHS FISCAL YEAR 2005 INFORMATION QUALITY REPORT

- I. Cover Sheet:** Requests for Correction by Agency
- Department Name:** Department of Health and Human Services (HHS)
- Period Covered:** FY 2005 (October 2004 through September 2005)

Web page location of agency information quality correspondence:
<http://aspe.hhs.gov/infoquality/requests.shtml>

Number of Information Quality Requests received in FY 05 by HHS (OPHS, NIH, FDA, CDC/ATSDR, and ACF) 5 Number designated as influential : 0

Number of Requests for Corrections HHS received in FY03 or FY 04 that HHS responded to in FY 05: 3

Number of Requests for Reconsideration (appeals) HHS received in FY03 or FY 04 that HHS responded to in FY 05: 2

1. **Agency Receiving Correction Request:** Department of Health and Human Services, Food and Drug Administration (FDA)
 - **Requestor:** Environmental Working Group (EWG), an advocacy group
 - **Date Received:** Letter dated December 22, 2003, delivered by U.S. Postal Mail and logged in by the Office of the Ombudsman, FDA on January 5, 2004.
 - **Summary of Request:** EWG requests correction of the 2003 FDA Consumption Draft Advisory regarding the risks of mercury contaminated fish and shellfish, specifically entitled “Advice for Women Who Are Pregnant, Who Might Become Pregnant, And Nursing Mothers, About Avoiding Harm to Your Baby or Young Child from Mercury in Fish and Shellfish.”
 - **Description of Requested Correction:** EWG recommended the following:
 - 1) FDA should conduct an updated, comprehensive sampling program for seafood.
 - 2) FDA should provide consumption advice that consumers can follow without appreciable risk to their health.
 - 3) FDA should provide specific advice on how much seafood young children can safely consume.
 - 4) FDA should provide specific advice on canned tuna.
 - 5) Calculation of risk on “exceedences” of the reference dose for the last half of the third trimester of pregnancy should be consistent with interpretations of the National Academy of Sciences 2000 report.
 - 6) FDA should develop and make public documentation of a scientific assessment conducted in correcting the 2003 Advisory.
 - **Influential:** ___ Yes ___ X ___ No ___ Undetermined
 - **First Agency Response:** ___ in progress ___ X ___ completed
 - **Resolution:** FDA responded to the six recommendations made by EWG. FDA also noted that EWG’s comments were helpful in refining the 2003 Draft Advisory which was released in final form in March 2004.
 - **Appeal Request:** ___ none ___ in progress ___ X ___ completed
 - **Judicial Review:** None
 - **Summary of Request for Reconsideration:** The EWG claimed that the FDA’s response was inadequate for five reasons: the recommendation on consumption would exceed safe levels of mercury exposure, the advisory is not based on the best available peer reviewed

science, there is vagueness in the amount children can consume, the Advisory did not undergo a rigorous peer review process, and the data relied up for the Advisory is inadequate and inconsistent with sound scientific practices.

- **Type of Appeal Process Used:** The appeal was reviewed and responded to by the Director of FDA's Center for Food Safety and Applied Nutrition.
- **Appeal Resolution** The FDA responded to the five reasons EWG presented and explained why it disagreed. Among the reasons, it noted that: the Advisory is not about what level of mercury exposure is "safe;" it is about risk reduction, the Advisory is soundly supported by data generated by EPA, FDA, and other experts within and outside of government, the Advisory reflects the ample and growing body of scientific literature supporting a determination that a well-balanced diet that includes a variety of fish and shellfish can contribute to the health of adults and children, and that it continues to sample various species of fish for mercury concentration and will update its data once analysis is complete. FDA also noted that the Information Quality Act was not designed to address policy and legal ramifications such as was presented by EWG .

2. Agency Receiving Correction Request: Department of Health and Human Services, Food and Drug Administration

- **Requestor:** Buc & Beardsley, a law firm on behalf of their client, McNeil Consumer & Specialty Products (McNeil).
- **Date Received:** Letter dated May 18, 2004 and logged in by the Office of the Ombudsman, FDA on May 19, 2004.
- **Summary of Request:** The request concerns the FDA's "Consumer Campaign on Safe Use of OTC Pain Products." The request maintains that the campaign misrepresents the relative safety of various (OTC) pain products by suggesting that acetaminophen products are less safe than nonsteroidal, anti-inflammatory drugs (NSAIDs).
- **Description of Requested Correction:** The complainant requests the following: (1) FDA should halt distribution of the current campaign which consists of advertisements entitled "Why is it important to know that all these medicines contain acetaminophen?" and "The best way to take your over-the-counter pain reliever? Seriously" an article in the FDA Consumer magazine, a memo to State Boards of Pharmacy on this issue, "Questions and Answers on Using Over-the-Counter Human Drug Products Containing Analgesic/Antipyretic Active Ingredients Safely;" and a brochure entitled, "The best way to take your over-the-counter pain reliever? Seriously," (2) FDA should correct the relevant documents before restarting the campaign, and (3) FDA should provide an opportunity for McNeil and other companies whose products are affected to comment prior

to restarting of the campaign and prior to the release of any future OTC pain relief drug campaigns.

- **Influential:** ___ Yes No ___ Undetermined
 - **First Agency Response:** ___ in progress completed
FDA responded on August 25, 2004
 - **Resolution:** The FDA did not agree that the campaign violates the Data Quality Act or Guidelines. Based on suggestions from the Nonprescription Drug Advisory Committee, which met on Sept. 19-20, 2002, the educational campaign was developed in accordance with agency policies and procedures. The documents were developed by a team of experts familiar with the drugs and communication specialists, it was focus group tested with the public, circulated and cleared by senior leaders within the FDA as well as by the Office of the Secretary of the Department of Health and Human Services.
 - **Appeal Request** ___ none ___ in progress completed on March 7, 2005
 - **Judicial Review:** none
 - **Summary of Request for Reconsideration:** The Request for Reconsideration states that FDA's campaign represents acetaminophen as being less safe than NSAIDs¹. McNeil contends that acetaminophen is not less safe than NSAIDs and that FDA's campaign is not objective and is inconsistent with the Federal Data Quality Act.
 - **Type of Appeal Process Used:** The Request for Reconsideration was reviewed and signed by the Acting Commissioner of the FDA.
 - **Appeal Resolution:** The FDA stated that the Request for Reconsideration did not contain any new information that would compel the Agency to amend the campaign at this time. However, the FDA noted that it is considering some modifications to the campaign.
3. **Agency Receiving Correction Request:** Department of Health and Human Services, National Institutes of Health (NIH), Office of the Director
- **Requestor:** Jerry A. Cook
Chemical Products Corporation
Corporation
 - **Date Received:** Request received February 6, 2004 by electronic submission

¹ Nonsteroidal anti-inflammatory drugs

- **Summary of Request:** The requestor challenged the information posted electronically in Draft Technical Report (TR494) concerning the toxicity and carcinogenicity studies of anthraquinone. The requestor claimed that Draft TR494 lacked “transparency and objectivity” and contained incomplete information necessary to evaluate the effects of anthraquinone.
 - **Description of Requested Correction:** The requestor asked that Draft TR494 be withdrawn and revised.
 - **Influential:** _____ Yes No _____ Undetermined
 - **First Agency Response:** _____ in progress completed
July 16, 2004
 - **Resolution:** NIH determined that the agency’s Guidelines were not applicable to the request because the challenge concerned a *draft* report, not a final statement that represented the views of the NIH. In addition, because the *draft* report at issue was subject to notice and public comment, these procedures were the appropriate mechanism for considering the requestor’s comments on the Draft TR494. Accordingly, the agency included the requestor’s submission in the public comment process.
 - **Appeal Request:** _____ none _____ in progress completed
January 31, 2005
 - **Summary of Request for Reconsideration:** The requestor maintains that although TR494 was a draft, the underlying scientific information contained in the draft was not sufficiently clear for public comment and peer review to be effective. According to the requestor, the alternative process of public comment and peer review will be flawed if the draft is not subject to the processes set forth in the Information Quality Guidelines.
 - **Type of Appeal Process Used:** Senior Official Review
 - **Appeal Resolution:** The NIH affirmed in its response to the request for reconsideration that the Guidelines were not applicable
 - **Judicial Review:** none
4. **Agency Receiving Correction Request:** Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Environmental Health Science (NIEHS), National Toxicology Program (NTP)
- **Requestor:** The Nickel Development Institute (NiDi),

The Nickel Producers Environment Research Association (NiPERA),
and
Inco, United States
Neil J. King, Lawyer
Wilmer, Cutler & Pickering

- **Date Received:** The request was dated 4/9/03 and received electronically on 4/18/03.
- **Summary of Request:** The request maintains that the discussion in the 10th Report on Carcinogens (RoC) listings of Nickel Compounds and Metallic Nickel does not comply with the OMB Guidelines or with the HHS and NIH Guidelines in the following respects:
 - 1) It does not comply with the 'objectivity' requirement of the OMB Guidelines because:
 - A) Information is not provided in an accurate, clear, complete and unbiased manner';
 - and B) It does not present 'accurate, reliable, and unbiased information.'
 - 2) Although the 10th RoC presents 'influential' scientific information relating to an analysis of risks to human health allegedly posed by exposure to nickel compounds and metallic nickel, it fails to comply with the scientific quality principles established by Congress in the Safe Drinking Water Act Amendments of 1996, as required by the OMB Guidelines, in that: A) It does not use the best available peer reviewed science; B) It does not identify studies that fail to support the carcinogenic effect; and C) It is not comprehensive, informative, and understandable.
- **Description of Requested Correction:** "NiDi, NiPERA, and Inco request that the material identified in the request be corrected and that an appropriately revised discussion of Nickel Compounds and Metallic Nickel be published and disseminated as a correction to the 10th RoC."
- **Influential:** ___ Yes ___ No ___ Undetermined
- **First Agency Response:** ___ in progress ___ completed.
- The NTP response was sent by mail on 10/24/03.
- **Appeal Request:** ___ none ___ in progress ___ completed
The NTP received the appeal dated November 17, 2003, by electronic mail on December 9, 2003
- **Summary of Request for Reconsideration:** The requestors claim that "the 10th RoC's discussion of Nickel Compounds and Metallic Nickel fails to comply with the requirements of the Information Quality Act, as implemented in the OMB, HHS, and NIH Guidelines." The request asks that the "appeal of NTP's denial of my April 9, 2003 request for correction of information be granted," the issues identified in the April 9, 2003 letter be corrected in the profiles of Nickel Compounds and Metallic Nickel in the 10th RoC, and the revised profile "be published and disseminated as a correction to the 10th RoC."

- **Type of Appeal Process Used:** Senior Official Review. The appeal response was sent October 27, 2004.
- **Appeal Resolution:** The 10th RoC complies with NIH Guidelines and the Information Quality Act in its discussions of Nickel Compounds and Metallic Nickel. This finding is based on a complete review of this case and the following key points: (1) the NTP presented the scientific information on Nickel Compounds and Metallic Nickel in a manner consistent with the recommendations made by all review groups, (2) the information in the profile follows the format and protocol used in developing the RoC, (3) the listing complies with the “objectivity” requirement of the NIH Guidelines, and (4) the review of Nickel Compounds and Metallic Nickel was rigorous and used all available science. However, the following clarifications and deletions will be made in the next edition of the RoC: the reference to mild steel welders will be deleted; the word “alone” [‘soluble nickel *alone*’] in the description of the Andersen et al. (1996) study will be deleted; the phrase “inadequate for evaluation” in the last sentence of the section, *Metallic Nickel* will be clarified; and a more detailed statement will be developed about the lack of nickel studies done in animals via oral or dermal exposure routes.
- **Judicial Review:** none

5) **Agency Receiving Correction Request:** Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Environmental Health Science (NIEHS), National Toxicology Program (NTP)

- **Requestor:** Vinyl Chloride Health Committee
American Chemistry Council
Courtney M. Price
Vice President, CHEMSTAR
- **Date Received:** The request was dated July 1, 2004 and received by electronic mail on July 7, 2004.
- **Summary of Request:** The request asks for the correction of information in the profile for vinyl chloride in the 11th and future editions of the Report on Carcinogens.
- **Description of Requested Correction:** The requestor asks that the NTP delete information in the carcinogenicity section of the profile for vinyl chloride.
- **Influential:** _____ Yes No _____ Undetermined
- **First Agency Response:** _____ in progress completed
Response dated January 18, 2005

- **Resolution:** The NTP noted that the program was already in the process of revising the summary profile on vinyl chloride for the 11th Report on Carcinogens and would address the issues raised in the revised profile. The NTP said that it would send a copy of the revised summary profile once the Secretary approved the 11th Report on Carcinogens.

The 11th report was released publicly on January 31, 2005. The NTP sent the revised profile on February 8, 2005

- **Appeal Request:** none in progress completed
- **Summary of Request for Reconsideration:** n/a
- **Type of Appeal Process Used:** n/a
- **Appeal Resolution:** n/a
- **Judicial Review:** none

6. Agency Receiving Correction Request: Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Environmental Health Science (NIEHS), National Toxicology Program (NTP)

- **Requestor:** Jim J. Tozzi
Center for Regulatory Effectiveness
Jere White
Kansas Corn Growers Association
Garry Marshall
Missouri Corn Growers Association
Stephanie Whalen
Hawaii Agriculture Research Center
Joel Nelsen
California Citrus Mutual
- **Date Received:** The request was dated July 16, 2004, and received by electronic mail on July 19, 2004.
- **Summary of Request:** The requestors said the information about atrazine and cancer published by the NTP in the Federal Register (69 FR 28940) is misleading and incomplete. The notice announced the NTP's intent to consider review of atrazine for possible listing in the 12th Report on Carcinogens and gives the basis for the nomination. The request stated that the notice should provide additional background about ongoing studies of atrazine and details about reviews by other scientific panels.

- **Description of Requested Correction:** The requestors asked the NTP to correct information in NTP's Federal Register notice that pertains to atrazine and to withdraw the part of the notice that addresses review of atrazine in the 12th Report on Carcinogens.
 - **Influential:** _____ Yes No _____ Undetermined
 - **First Agency Response:** _____ in progress completed
Response dated May 25, 2005
 - **Resolution:** The NTP disagreed with the requestors' statement that information in the Federal Register notice needs correction and pointed out that the notice is not a definitive statement that the substance will be listed in the Report on Carcinogens. The agency noted that the intent of the notice is to alert the public to substances under consideration for the Report on Carcinogens, to provide a basis for why the substances were nominated for review, and to invite public comment on the nominations. The NTP also indicated that the notice was not intended to provide a full literature review on any nomination. The NTP said the notice meets the standards in the NIH Guidelines and pointed out that the policy decision regarding whether the NTP reviews atrazine is not subject to review under the Information Quality Act.
 - **Appeal Request:** _____ none in progress _____ completed
Appeal received June 24, 2005
 - **Summary of Request for Reconsideration:** The appeal asks that the denial of the request for correction be overturned. The appeal states that the NTP dissemination of the Federal Register notice announcing that atrazine is nominated for review to the RoC is misleading, inaccurate, and biased because it does not present the full IARC findings in stating the reason for the nomination.
 - **Type of Appeal Process Used:** n/a
 - **Appeal Resolution:** n/a
 - **Judicial Review:** none
7. **Agency Receiving Correction Request:** Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Environmental Health Science (NIEHS), National Toxicology Program (NTP)
- **Requestor:** Jim J. Tozzi
Center for Regulatory Effectiveness
Jere White
Kansas Corn Growers Association

Garry Marshall
Missouri Corn Growers Association
Stephanie Whalen
Hawaii Agriculture Research Center
Greg Shelor
Kansas Grain Sorghum Products Association
Joel Nelsen
California Citrus Mutual

- **Date Received:** The request was dated June 28, 2004, and received by electronic mail on July 1, 2004
- **Summary of Request:** The requestors state that the NTP notice published in the Federal Register (69 FR 28940) contains conflicting information about the procedures that will be used for review of nominations to the 12th Report on Carcinogens.
- **Description of Requested Correction:** The requestors ask that the NTP withdraw the Federal Register notice (69 FR 28940) and not publish another notice until the program decides what procedures will apply for review of nominations to the 12th Report on Carcinogens and publishes them as final.
- **Influential:** _____ Yes No _____ Undetermined
- **First Agency Response:** _____ in progress completed
Response dated February 16, 2005
- **Resolution:** The NTP noted that the Federal Register notice served to identify the substances under consideration for the 12th Report on Carcinogens and to invite public comments on them. The notice only included a brief description of the process for review of nominations and was not intended as a complete explanation of the process. The NTP held a public meeting in January 2005 to gain public input about possible revisions to the process for review of nominations. The NTP acknowledged that the review process was not finalized and posted on its website prior to publication of the Federal Register notice, but also observed that the NTP finalized the revised review process and posted it on the NTP website on October 20, 2004.
- **Appeal Request:** none _____ in progress _____ completed
- **Summary of Request for Correction of Information:** n/a
- **Type of Appeal Process Used:** n/a
- **Appeal Resolution:** n/a
- **Judicial Review:** none

8. Agency Receiving Correction Request: Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Environmental Health Science (NIEHS), National Toxicology Program (NTP)

- **Requestor:** Naphthalene Panel
American Chemistry Council
Courtney M. Price
Vice President, CHEMSTAR
- **Date Received:** The request was dated April 1, 2004, and received by electronic mail on April 1, 2004.
- **Summary of Request:** The request asks that the NTP do the following: 1) correct three documents: the Background Document for Naphthalene and Summaries of the NIEHS/NTP Review Group 1 and NTP Executive Committee Interagency Working Group (RG2) for the Report on Carcinogens (RoC) meetings; 2) rescind the meetings of the RG2 and the NTP Board of Scientific Counselors RoC Subcommittee; and 3) hold new meetings of both groups. As an alternative, the request asks that the NTP staff, NIH's Office of Communications and Public Liaison (OPCL), and the NTP Executive Committee "undertake a comprehensive pre-dissemination review of the entire record of the listing proceeding as it relates to naphthalene before any recommendation is made concerning listing naphthalene in the Eleventh RoC by the NTP Director."
- **Description of Requested Correction:** The request states that "[t]he best and only appropriate solution to these violations is for the NTP to rescind the November 19, 2002, vote of the RoC Subcommittee on the listing of naphthalene, rescind the RG2 review summary, withdraw the Background Document from the NTP's website and otherwise cease dissemination of that document, correct the Background Document so that it comports with the OMB, NIH, and HHS Guidelines, make the corrected document publicly available, and arrange for repeats of the RG2 and NTP RoC Subcommittee meetings that comport with the OMB, NIH, and HHS Guidelines, to be held after issuance of the corrected Background Document. NTP should also correct the RG1 and, if not rescinded, the RG2 review summaries to provide the necessary detail to satisfy the objectivity and utility requirements."

"Alternatively, if this remedy is not granted, the Panel requests that NTP staff, NIH's OPCL, and the NTP Executive Committee engage in a well-defined process of pre-dissemination review of the entire naphthalene record with regard to the data quality standards under the NIH, OMB, and HHS Guidelines before the NTP Executive Committee makes its recommendation to the NTP Director."

- **Influential:** Yes No Undetermined Under Appeal
- **First Agency Response:** in progress completed
Response dated January 18, 2005

- **Resolution:** The agency disagreed with the requestor and said that the Background Document and RG1 and RG2 summaries satisfy both the HHS and NIH Guidelines for Information Quality. The NTP response discussed the process for development of the Background Document and the type of information that it would contain. The response addressed scientific issues raised in the complaint concerning the study findings presented in the Background Document. The NTP explained that the Background Document on Naphthalene, the RG1 and RG2 review summaries satisfied the applicable information quality guidelines. The NTP noted that the conduct of the meetings of the RG2 and RoC Subcommittee is not subject to the Information Quality Act.
- **Appeal Request:** none X in progress* completed
Appeal dated February 18, 2005
*Response sent November 2, 2005 (after the end of FY 2005)
- **Summary of Request for Reconsideration:** n/a
- **Type of Appeal Process Used:** n/a
- **Appeal Resolution:** n/a
- **Judicial Review:** none

9. Agency Receiving Petition: Department of Health and Human Services, Office of Public Health and Science, Office of Disease Prevention and Health Promotion

- **Requestor:** a private citizen
- **Date Received:** Letter sent by postal mail dated July 14, 2004 and logged in on July 26, 2004
- **Summary of Request:** The requestor states that, as of the date of his letter, the organizations and Web sites in the healthfinder@ pertaining to complementary and alternative medicine do not meet the published healthfinder@ selection criteria.
- **Description of Requested Correction:** The request seeks the de-listing from healthfinder@ of the complementary and alternative medicine organizations and Web sites identified by the requestor because they do not meet healthfinder@ selection standards, and the inclusion of other sites identified by the requestor as meeting the standards.
- **Influential:** Yes X No undecided/unsure

- **First Agency Response:** ___ in progress X completed
- **Resolution:** The response to the requestor was sent on December 12, 2004. The Office of Disease Prevention and Health Promotion (ODPHP) determined that the Information Quality Guidelines were not the appropriate mechanism to articulate or respond to the issues raised by the requestor. The requestor had sent several other letters and electronic mail messages raising the same issues to ODPHP and the Assistant Secretary for Health. ODPHP responded in writing to the issues in a letter sent October 27, 2004.
- **Appeal Request:** X none ___ in progress ___ completed
- **Summary of Request for Reconsideration:** n/a
- **Type of Appeal Process Used:** n/a
- **Judicial Review:** none

10. **Agency Receiving Correction Request:** Department of Health and Human Services (DHHS)

- **Requestor:** Americans for Safe Access (ASA), an advocacy group
- **Date Received:** October 15, 2004 (request dated October 4, 2004)
- **Summary of Request:** In 2001, the Department of Health and Human Services reviewed the Marijuana Rescheduling Petition of 1995. That review concluded that marijuana has no currently accepted medical use in treatment in the United States. The petitioner alleges that HHS misstates the scientific evidence and ignores numerous reports and studies demonstrating the medical utility of marijuana and its constituent compounds. The petitioner further alleges that dissemination of this information violates the Information Quality Act.
- **Description of Requested Correction:** The Notice of Denial of the petition to reschedule marijuana appears on government websites and in the *Federal Register*, Vol. 66, p. 20038,

April 18, 2001. ASA has requested that several statements from that denial be removed and replaced with statements provided by ASA.

- **Influential:** ___ Yes ___ No ___ Undetermined
- **First Agency Response:** ___ in progress ___ completed
The response was sent on April 20, 2005.
- **Resolution:** The response states that DHHS is currently in the process of conducting a review in response to the petition for change that was submitted to DEA in October 2002, by the Coalition for Rescheduling Cannabis. In the course of that review DHHS will evaluate all the publicly available peer reviewed literature on the efficacy of marijuana.
- **Appeal Request:** ___ none ___ in progress ___ completed Appeal dated May 19, 2005, received in the Office of the Ombudsman May 20, 2005.
- **Summary of Request for Reconsideration:** ASA asserts that HHS has failed to correct its inaccurate statements that marijuana lacks medical use. This violates the goal of the Data Quality Act, the Paperwork Reduction Act, and the HHS implementing guidelines. ASA further objects to the “lumping” of their Request for Correction with the much slower process of the Drug Enforcement Administration’s review of a petition to change the schedule of marijuana.
- **Type of Appeal Process Used:** n/a
- **Judicial Review:** none

11. Agency Receiving Correction Request: Department of Health and Human Services, National Institutes of Health (NIH), National Institute of Environmental Health Science (NIEHS), National Toxicology Program (NTP)

- **Requestor:** Airepel Humane Bird Management Service
Ken Ballinger
Vice President
Airepel
- **Date Received:** The request was dated January 18, 2005 and received by electronic mail on January 21, 2005.
- **Summary of Request:** The requestor asks for correction of information in the Draft NTP Technical Report 494 on Anthraquinone. The requested corrections include changes to the text, abstract, and title of the draft printed and website posted report.

- **Description of Requested Correction:** The request ask for the following:
 1. Correction of the NTP study TR 494 to resolve the conflicted science as reviewed in discrepancy resolution document.
 2. Correction of the NTP study TR 494 to include the peer reviewed literature specific to the study.
 3. Correction of the NTP study TR 494 abstract to reflect the changes in the body of the text.
 4. Correction of the Title of the NTP study 494 to reflect the actual nature of the sample tested to read “Toxicology and Carcinogenesis Studies of Mutagen Contaminated Anthraquinone (CAS No. 84-65-1) in F344/N Rats and B6C3F₁ Mice (Feed Studies)”.
 5. Correction of all related web site postings of the current text and abstract of the study.
 6. Explanation by the NTP of the apparent non-homogeneity of lot 5893 used in the bioassay.
 7. 40 CFR Part 792.105 (a) requires the method of synthesis of a test article to be documented for each sample of a test article. NTP should follow these guidelines and account for the contaminants that result.

- **Influential:** _____ Yes ___ ___ No _____ Undetermined

- **First Agency Response:** ___ in progress ___ ___ completed
The response was dated April 21, 2005

- **Resolution:** The NIH noted that the Draft NTP Technical Report is not subject to the Information Quality Act (IQA) because it does not represent the agency’s views. The draft report had the appropriate disclaimer alerting the audience that it does not represent the official opinion of the government. It is a draft report circulated for peer review. The NTP handled the complaint as part of the existing mechanism for public comment on the draft report.

- **Appeal Request:** ___ ___ none _____ in progress _____ completed

- **Summary of Request for Reconsideration:** n/a

- **Type of Appeal Process Used:** n/a

- **Appeal Resolution:** n/a

- **Judicial Review:** none

- 12. **Agency Receiving Correction Request:** Department of Health and Human Services (DHHS)

- **Requestor:** Omega Laboratories, Inc., a drug-testing company

- **Date Received:** May 23, 2005, received via electronic mail with hard-copy and attachments. The letter itself is not dated.
- **Summary of Request:** Omega requests that a letter sent by FDA's Center for Devices and Radiological Health to the firm in December 2003, be removal from the FDA Website. <http://www.fda.gov/cdrh/oivd/letters/120103-omega.html> The petitioner asserts that the letter is inaccurate.
- **Description of Requested Correction:** Omega requests that the letter be immediately removed from the FDA Website. Omega also notes that they responded to the letter on December 3, 2003, but have received no further correspondence from the FDA.
- **Influential:** ___ Yes No ___ Undetermined
- **First Agency Response:** in progress ___ completed
- **Resolution:**
- **Appeal Request:** ___ none ___ in progress ___ completed
- **Summary of Request for Reconsideration:**
- **Type of Appeal Process Used:**
- **Appeal Resolution:**

13. Agency Receiving Correction Request: United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR)/CDC.

- **Requestor:** a private citizen
- **Date Received:** Internet request dated July 26, 2005
- **Summary of Request:** The request initially describes a June 16, 2005 joint press release issued by the Illinois Attorney General, Illinois Department of Public Health, Illinois Environmental Protection Agency (EPA), Illinois Department of Natural Resources, and the U.S. EPA. The request also specifically questions the ATSDR Public Health Assessment at Illinois Beach State Park (IBSP PHA) dated June 6, 2000. The requestor states the IBSP PHA "used sampling strategies and analytical methods that have been proven by Federal research to have no correlation to health risk. This includes the use of 1) a "hybrid" asbestos bulk sampling and analytical method; 2) inappropriate use of

personal and aggressive air clearance testing; and, 3) failure to differentiate the higher risk from exposure to amphibole asbestos fibers as a means to measure asbestos health risks from asbestos contaminated beach sand. In addition, new analytical testing performed at the site by Dr. D. Wayne Berman (Waukegan Park District study 2002) identified tremolite asbestos and the University of Illinois-Chicago (IBSP: Determination of Asbestos Contamination, 2005) identified the presence of "significantly elevated" levels of serpentine AND amphibole asbestos fibers (greater than 10 microns) including tremolite asbestos in the study area."

- **Description of Requested Correction:** The requestor asked that the IBSP PHA be precluded from being cited or quoted as a valid public health assessment. The requestor states, "If this report is withdrawn the State of Illinois would have to perform a scientifically sound human health risk assessment."
- **Influential:** ___ Yes ___ No ___ Undetermined
- **First Agency Response:** ___ x ___ in progress ___ completed
- **Resolution:** n/a
- **Appeal Request:** ___ none ___ in progress ___ n/a
- **Summary of Request for Reconsideration:** n/a
- **Type of Appeal Process Used:** n/a
- **Appeal Resolution:** n/a
- **Judicial Review:** none

14. Agency Receiving Correction Request: U.S. Department of Health and Human Services (HHS), Administration for Children and Families (ACF), Administration for Children, Youth and Families (ACYF), Family and Youth Services Bureau (FYSB), Community-Based Abstinence Education program (CBAE)

- **Requestor:** James Wagoner
Advocates for Youth and
William Smith
Sexuality Information Education Council of the US (SIECUS)

- **Date Received:** The request was dated September 13, 2005 and received by electronic transmission on September 13, 2005.
- **Summary of Request:** The requestors challenge the quality of data and information disseminated through ACF's Community-Based Abstinence Education (CBAE) grant program. The requesters charge that ACF is in violation of the Information Quality Act of 2000 through its "dissemination of inaccurate and misleading information about the prevention of teenage pregnancy, HIV and other STDS" through its funding of CBAE grantees.
- **Description of Requested Correction:** The request seeks to have HHS/ACF "cease sponsorship of those CBAE grantees that fail to provide medically accurate, complete sexual health information."
- **Influential:** ___ Yes ___ No ___ Undetermined
- **First Agency Response:** in progress ___ completed
- **Resolution:**
- **Appeal Request:** ___ none ___ in progress ___ completed
- **Summary of Request for Reconsideration:** n/a
- **Type of Appeal Process Used:** n/a
- **Appeal Resolution:** n/a
- **Judicial Review:** none

2006 Year-End Information Quality Report

Section I

I. Cover Sheet: Requests for Correction Received FY 2006 (Oct 1, 2005 to Sept 30, 2006)

Department Name: Health and Human Services

Web page location of department information quality correspondence: <http://aspe.hhs.gov/infoquality/>

<u>Agency Name</u>	<u>Number of Requests Received</u>
<u>FDA</u>	<u>2</u>
<u>NIH</u>	<u>2</u>
<u>CDC/ATSDR</u>	<u>1</u>
<u>SAMHSA</u>	<u>2</u>
<u> </u>	<u> </u>
<u>TOTAL</u>	<u>7</u>

SECTION II

II. If you received correction requests or appeals and did not provide a final response in FY03, FY04 or FY05 please list those correction requests below and provide a detailed summary in section IV of this template.

<u>Agency Name</u>	Number of Outstanding Requests from FY03, FY04, or FY05 which were responded to in FY06 or are still incomplete		Number of Appeals Received in FY03, FY04, or FY05, which were responded to in FY06 or are still Incomplete	
	<u>Complete</u>	<u>Still Incomplete</u>	<u>Complete</u>	<u>Still Incomplete</u>
<u>FDA</u>	<u> </u>	<u>1</u>	<u> </u>	<u> </u>
<u>NIH</u>	<u> </u>	<u> </u>	<u>1</u>	<u> </u>
<u>CDC/ATSDR</u>	<u> </u>	<u> </u>	<u>1</u>	<u> </u>
<u>OPHS</u>	<u> </u>	<u> </u>	<u>1</u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
TOTAL	<u> </u>	<u>1</u>	<u>3</u>	<u> </u>

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.	
Agency/SubAgency Receiving Correction Request	HHS/Centers for Disease Control and Prevention (CDC) Agency for Toxic Substances and Disease Registry (ATSDR)
Agency Request Name or Number (if applicable):	25. ATSDR/CDC - Mixture Guidance
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/25a.shtml
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual
	<input checked="" type="checkbox"/> Trade Group (.com)
	<input type="checkbox"/> Trade Group (.org)
	<input type="checkbox"/> Corporation
	<input type="checkbox"/> Law Firm on behalf of:
	<input type="checkbox"/> Individual
	<input type="checkbox"/> .com <input type="checkbox"/> .org
<input type="checkbox"/> Other (please describe):	
Date Received:	date: December 5, 2005
Date Responded to (please mark column B with an X if still pending):	date: September 12, 2006
	<input type="checkbox"/> Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/25b4.pdf
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/> Still Pending
	<input type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input checked="" type="checkbox"/> No Correction
	<input type="checkbox"/> Disclaimer added to information on website
<input type="checkbox"/> Request was handled under a different process (please describe below):	
<input type="checkbox"/> Changes, other than those requested were made (please describe below):	
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assessment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
<input checked="" type="checkbox"/> Website	
<input type="checkbox"/> Other (please describe below):	
Has An Appeal been filed?	<input type="checkbox"/> Yes
	<input checked="" type="checkbox"/> No

If an Appeal on this request has been filed in FY06 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this:	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.

Agency/SubAgency Receiving Correction Request	HHS/Substance Abuse and Mental Health Services Administration
Agency Request Name or Number (if applicable):	26. SAMHSA - Smokeless Tobacco Risks
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/26a.shtml
Requestor Affiliation (please mark appropriate choice with an X in column B);	<input type="checkbox"/> Private Individual
	<input checked="" type="checkbox"/> Trade Group (.com)
	<input type="checkbox"/> Trade Group (.org)
	<input type="checkbox"/> Corporation
	<input type="checkbox"/> Law Firm on behalf of:
	<input type="checkbox"/> Individual
	<input type="checkbox"/> .com
	<input type="checkbox"/> .org
	Other (please describe):
Date Received:	date: December 22, 2005
Date Responded to (please mark column B with an X if still pending):	date: May 10, 2005
	<input type="checkbox"/> Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/26b2.shtml
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/> Still Pending
	<input type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input type="checkbox"/> No Correction
	<input type="checkbox"/> Disclaimer added to information on website
	<input type="checkbox"/> Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below): Information removed from website pending review.
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assesment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
	<input checked="" type="checkbox"/> Website
	Other (please describe below):
Has An Appeal been filed?	<input type="checkbox"/> Yes
	<input checked="" type="checkbox"/> No

If an Appeal on this request has been filed in FY06 you must fill out the rest of this form (otherwise leave blank):	
Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this	No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.	
Agency/SubAgency Receiving Correction Request	HHS/ National Institutes of Health (NIH)
Agency Request Name or Number (if applicable):	27. NIH - Smokeless Tobacco Ingredients
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/27a.shtml
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual
	<input type="checkbox"/> Trade Group (.com)
	<input type="checkbox"/> Trade Group (.org)
	<input checked="" type="checkbox"/> Corporation
	<input type="checkbox"/> Law Firm on behalf of:
	<input type="checkbox"/> Individual
	.com
	.org
	Other (please describe):
Date Received:	date: April 3, 2006
Date Responded to (please mark column B with an X if still pending):	date: September 5, 2006 <input type="checkbox"/> Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/27b2.pdf
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/> Still Pending
	<input checked="" type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input type="checkbox"/> No Correction
	<input type="checkbox"/> Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assesment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
	<input checked="" type="checkbox"/> Website
	Other (please describe below):
Has An Appeal been filed?	<input type="checkbox"/> Yes
	<input checked="" type="checkbox"/> No

If an Appeal on this request has been filed in FY06 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this:	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.

Agency/SubAgency Receiving Correction Request	HHS/National Institutes of Health (NIH) Toxicology Program (NTP)	National
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Agency Request Name or Number (if applicable):	28. NTP - Technical Report 494 (Anthraquinone)
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Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/28a.pdf
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Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input checked="" type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	Other (please describe):

Date Received:	date: June 6, 2006
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Date Responded to (please mark column B with an X if still pending):	date:
	<input checked="" type="checkbox"/> Still pending

Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/28b1.pdf
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Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input checked="" type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
<input type="checkbox"/>	Changes, other than those requested were made (please describe below):	

Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input checked="" type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assessment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input type="checkbox"/>	Website
<input type="checkbox"/>	Other (please describe below):	

Has An Appeal been filed?	Yes
	<input checked="" type="checkbox"/> No

If an Appeal on this request has been filed in FY06 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.

Agency/SubAgency Receiving Correction Request	HHS/food and Drug Administration (FDA)
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Agency Request Name or Number (if applicable):	29. FDA - Wound Therapy
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Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/29a.pdf
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Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input checked="" type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	.com
<input type="checkbox"/>	.org	
<input type="checkbox"/>	Other (please describe):	

Date Received:	date: May 23, 2006
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Date Responded to (please mark column B with an X if still pending):	date: July 31, 2006
	<input type="checkbox"/> Still pending

Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/29b2.pdf
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Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
<input checked="" type="checkbox"/>	Changes, other than those requested were made (please describe below): No correction was made, but an addendum was added to the article on the website	

Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assessment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input checked="" type="checkbox"/>	Website
<input type="checkbox"/>	Other (please describe below):	

Has An Appeal been filed?	<input type="checkbox"/>	Yes
	<input checked="" type="checkbox"/>	No

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this:	No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.

Agency/SubAgency Receiving Correction Request:	HHS/SAMHSA
Agency Request Name or Number (if applicable):	30. SAMHSA - Smokeless Tobacco
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/30a.pdf
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual
	<input type="checkbox"/> Trade Group (.com)
	<input checked="" type="checkbox"/> Trade Group (.org)
	<input type="checkbox"/> Corporation
	Law Firm on behalf of:
	Individual .com .org
	Other (please describe):
Date Received:	date: June 16, 2006
Date Responded to (please mark column B with an X if still pending):	date: August 10, 2006
	<input type="checkbox"/> Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/30b1.pdf
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/> Still Pending
	<input type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input type="checkbox"/> No Correction
	<input type="checkbox"/> Disclaimer added to information on website
	<input type="checkbox"/> Request was handled under a different process (please describe below):
<input checked="" type="checkbox"/> Changes, other than those requested were made (please describe below): Information removed from website pending review.	
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assessment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
	<input checked="" type="checkbox"/> Website
<input type="checkbox"/> Other (please describe below):	
Has An Appeal been filed?	<input type="checkbox"/> Yes
	<input checked="" type="checkbox"/> No

If an Appeal on this request has been filed in FY06 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this:	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending Full Correction Partial Correction No Correction Disclaimer added to information on website Request was handled under a different process (please describe below): Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY06.

Agency/SubAgency Receiving Correction Request	HHS/Food and Drug Administration (FDA)
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Agency Request Name or Number (if applicable):	31. FDA - Allergens Threshold Report
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Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/31a.pdf
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Requestor Affiliation (please mark appropriate choice with an X in column B):	<input checked="" type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	.com
	<input type="checkbox"/>	.org
		Other (please describe):

Date Received:	date: August 2, 2006
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Date Responded to (please mark column B with an X if still pending):	date:	
	<input checked="" type="checkbox"/>	Still pending

Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/31b1.pdf
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Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input checked="" type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
		Changes, other than those requested were made (please describe below):

Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input checked="" type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assessment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input type="checkbox"/>	Website
		Other (please describe below):

Has An Appeal been filed?	Yes
	No

If an Appeal on this request has been filed in FY06 you must fill out the rest of this form (otherwise leave blank):	
Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this:	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section IV. Please fill out this form for EACH Outstanding Correction Request from FY03, FY04, or FY05 which was completed in FY06 or is still pending. If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must include description of the correction request and appeal.

Agency/SubAgency Receiving Correction Request	HHS/Office of Public Health and Science (OPHS)
Agency Request Name or Number (if applicable):	20. Medical Marijuana
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/20a.pdf
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual
	<input type="checkbox"/> Trade Group (.com)
	<input checked="" type="checkbox"/> Trade Group (.org)
	<input type="checkbox"/> Corporation
	Law Firm on behalf of: <input type="checkbox"/> Individual <input type="checkbox"/> .com <input type="checkbox"/> .org
	<input type="checkbox"/> Other (please describe):
Date Received:	date: October 6, 2004
Date Responded to (please mark column B with an X if still pending):	date: April 20, 2005 <input type="checkbox"/> Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/20d7.pdf
Request Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Still Pending
	<input type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input checked="" type="checkbox"/> No Correction
	<input type="checkbox"/> Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assessment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
	<input type="checkbox"/> Website
<input checked="" type="checkbox"/> Other (please describe below): Federal Register Notice	

Has An Appeal been filed?	<input checked="" type="checkbox"/>	Yes
		No
If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must fill out the rest of this form (otherwise leave blank):		
Link to Appeal Request:		
Date of Appeal request:	date:	May 20, 2005
Date Appeal Responded to (please mark column B with an X if still pending):	date:	July 12, 2006
		<input type="checkbox"/> Still pending
Link to Appeal Response:		
Appeal Process used (please describe mechanism used in a few sentences):	Senior official review	
Is there any judicial review associated with this	<input checked="" type="checkbox"/>	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):		Still Pending
		Full Correction
		Partial Correction
	<input checked="" type="checkbox"/>	No Correction
		Disclaimer added to information on website
		Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):	
<p>Description of Request: In 2001, the Department of Health and Human Services reviewed the Marijuana Rescheduling Petition of 1995. That review concluded that marijuana has no currently accepted medical use in treatment in the United States. The requestor argues that HHS misstated the scientific evidence and ignored numerous reports and studies demonstrating the medical utility of marijuana and its constituent compounds. The requestor asserts that HHS has failed to correct its inaccurate statements that marijuana lacks medical use. This violates the goal of the Data Quality Act, the Paper Reduction Act and the HHS implementing guidelines. The requestor further objects to the "jumping" of their Request for Correction with the much slower process of the Drug Enforcement Administration's review of a petition to change the schedule of marijuana.</p>		

Section IV. Please fill out this form for EACH Outstanding Correction Request from FY03, FY04, or FY05 which was completed in FY06 or is still pending. If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must include description of the correction request and appeal.

Agency/SubAgency Receiving Correction Request	HHS/NIH/NTP	
Agency Request Name or Number (if applicable):	14. NTP-Napthalene	
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/14a.pdf	
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Private Individual
	<input checked="" type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	.com
	<input type="checkbox"/>	.org
	<input type="checkbox"/>	Other (please describe):
Date Received:	date: April 1, 2004	
Date Responded to (please mark column B with an X if still pending):	date: January 18, 2005	
	<input type="checkbox"/> Still pending	
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/14b4.pdf	
Request Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input checked="" type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
	<input type="checkbox"/>	Changes, other than those requested were made (please describe below):
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assessment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input type="checkbox"/>	Website
	<input checked="" type="checkbox"/>	Other (please describe below): Background material for Committee

Has An Appeal been filed?	<input checked="" type="checkbox"/>	Yes
		No
If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must fill out the rest of this form (otherwise leave blank):		
Link to Appeal Request:	http://aspe.hhs.gov/infoquality/request&response/14c.pdf	
Date of Appeal request:	date: February 18, 2005	
Date Appeal Responded to (please mark column B with an X if still pending):	date: November 2, 2005	<input type="checkbox"/> Still pending
Link to Appeal Response:	http://aspe.hhs.gov/infoquality/request&response/14d4.shtml	
Appeal Process used (please describe mechanism used in a few sentences):		
Is there any judicial review associated with this:	<input checked="" type="checkbox"/>	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input checked="" type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	Request was handled under a different process (please describe below):	
	Changes, other than those requested were made (please describe below):	
Summary of Request: The request asks that the NTP do the following: 1) correct three documents: the Background Document for Naphthalene and Summaries of the NIEHS/NTP Review Group 1 and NTP Executive Committee Interagency Working Group (RG2) for the Report on Carcinogens (RoC) meetings; 2) rescind the meetings of the RG2 and the NTP Board of Scientific Counselors RoC Subcommittee; 3) hold new meeting of both groups. As an alternative, the request asks that the NTP staff, NIH's Office of Communications and Public Liaison (OPCL), and the NTP Executive Committee "undertake a comprehensive pre-dissemination review of the entire record of the listing proceeding as it relates to naphthalene before any recommendation is made concerning listing naphthalene in the Eleventh RoC by the NTP Director."		

Section IV. Please fill out this form for EACH Outstanding Correction Request from FY03, FY04, or FY05 which was completed in FY06 or is still pending. If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must include description of the correction request and appeal.

Agency/SubAgency Receiving Correction Request:	HHS/Food and Drug Administration (FDA)
Agency Request Name or Number (if applicable):	22. FDA-OMEGA Letter
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/22a.shtml
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual
	<input type="checkbox"/> Trade Group (.com)
	<input type="checkbox"/> Trade Group (.org)
	<input checked="" type="checkbox"/> Corporation
	<input type="checkbox"/> Law Firm on behalf of:
	<input type="checkbox"/> Individual
	.com
	.org
	Other (please describe):
Date Received:	date: May 23, 2005
Date Responded to (please mark column B with an X if still pending):	date: <input type="checkbox"/> Still pending
Link to Agency Response:	
Request Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Still Pending
	<input type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input type="checkbox"/> No Correction
	<input type="checkbox"/> Disclaimer added to information on website
	<input checked="" type="checkbox"/> Request was handled under a different process (please describe below): Non-compliance letter was sent to Omega
	Changes, other than those requested were made (please describe below):
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assessment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
	<input checked="" type="checkbox"/> Website
	Other (please describe below): On December 5, 2005, FDA responded in writing to Omega's challenge regarding the applicability of specified FDA regulations to Omega's hair sample collection products. Issued in accordance with 21 CFR 10.75, FDA's regulation on internal agency review of decisions, this letter reaffirmed the applicability of FDA regulation cited in FDA's December 1, 2003 letter to Omega.

Has An Appeal been filed?	<input type="checkbox"/>	Yes
	<input checked="" type="checkbox"/>	No
If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must fill out the rest of this form (otherwise leave blank):		
Link to Appeal Request:		
Date of Appeal request:	date:	
Date Appeal Responded to (please mark column B with an X if still pending):	date:	Still pending
Link to Appeal Response:		
Appeal Process used (please describe mechanism used in a few sentences):		
Is there any judicial review associated with this	<input type="checkbox"/>	Yes (if yes please describe):
	<input type="checkbox"/>	No
Appeal Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
<input type="checkbox"/>	Changes, other than those requested were made (please describe below):	
<p>Summary of Request: Omega Laboratories, Inc. (Omega) filed a request for correction on May 23, 2005 for the removal of a letter sent to Omega by FDA that appeared on FDA's website. FDA's letter to Omega discussed FDA's regulatory concerns with Omega's hair sample collection products.</p>		

Section IV. Please fill out this form for EACH Outstanding Correction Request from FY03, FY04, or FY05 which was completed in FY06 or is still pending. If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must include description of the correction request and appeal.

Agency/SubAgency Receiving Correction Request	HHS/CDC/ATSDR	
Agency Request Name or Number (if applicable):	23. CDC Illinois Beach Park Assessment	
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/23a.shtml	
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input checked="" type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	.com
	<input type="checkbox"/>	.org
	<input type="checkbox"/>	Other (please describe):
Date Received:	date:	July 26, 2005
Date Responded to (please mark column B with an X if still pending):	date:	December 6, 2005
	<input type="checkbox"/>	Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/23b2.shtml	
Request Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input checked="" type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
<input type="checkbox"/>	Changes, other than those requested were made (please describe below):	
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assessment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input checked="" type="checkbox"/>	Website
<input type="checkbox"/>	Other (please describe below):	

Has An Appeal been filed?	<input checked="" type="checkbox"/>	Yes
	<input type="checkbox"/>	No
If an Appeal has been filed in FY06 on an FY03, FY04, or FY05 request you must fill out the rest of this form (otherwise leave blank):		
Link to Appeal Request:	http://aspe.hhs.gov/infoquality/request&response/23c1i.pdf ;	
	http://aspe.hhs.gov/infoquality/request&response/23c1ii.pdf	
Date of Appeal request:	date: December 23, 2005	
Date Appeal Responded to (please mark column B with an X if still pending):	date: July 20, 2006	<input type="checkbox"/> Still pending
Link to Appeal Response:	http://aspe.hhs.gov/infoquality/request&response/23d2.pdf	
Appeal Process used (please describe mechanism used in a few sentences):	Senior official review	
Is there any judicial review associated with this	<input checked="" type="checkbox"/>	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
	<input type="checkbox"/>	Changes, other than those requested were made (please describe below):
<p>Summary of Request: The request initially describes a June 16, 2005 joint press release issued by the Illinois Attorney General, Illinois Department of Public Health, Illinois Environmental Protection Agency (EPA), Illinois Department of Natural Resources, and the U.S. EPA. The request also specifically questions the ATSDR Public Health Assessment at Illinois Beach State Park (IBSP PHA) dated June 6, 2000. The requestor states the IBSP PHA "used sampling strategies and analytical methods that have been proven by Federal research to have no correlation to health risk. This includes the use of 1) a "hybrid" asbestos bulk sampling and analytical method; 2) inappropriate use of personal and aggressive air clearance testing; and 3) failure to differentiate the higher risk from exposure to amphibole asbestos fibers as a means to measure asbestos health risks from asbestos contaminated beach sand.</p> <p>In addition, new analytical testing performed at the site by Dr. D. Wayne Berman (Waukegan park District study 2002) identified tremolite asbestos and the University of Illinois-Chicago (IBSP: determination of Asbestos Contamination, 2005) identified the presence of "significantly elevated" levels of serpentine and amphibole asbestos fibers (greater than 10 microns) including tremolite asbestos in the study area.</p>		

SECTION II

II. If you received correction requests or appeals and did not provide a final response in FY03, FY04 or FY05 please list those correction requests below and provide a detailed summary in section IV of this template.

<u>Agency Name</u>	Number of Outstanding Requests from FY03, FY04, FY05, or FY06 that were completed to in FY07 or <u>are still incomplete</u>		Number of Appeals Received in FY03, FY04, FY05, or FY06 that were completed in FY07 or <u>are still incomplete</u>	
	<u>Complete</u>	<u>Still Incomplete</u>	<u>Complete</u>	<u>Still Incomplete</u>
HHS				
FDA	1	1	1	
NTP/NIH				1
TOTAL	1	1	1	1

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY07.

Agency/SubAgency Receiving Correction Request	FDA	
Agency Request Name or Number (if applicable):	Genasense	
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/32a.pdf	
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input type="checkbox"/>	Corporation
	<input checked="" type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input checked="" type="checkbox"/>	.com
	<input type="checkbox"/>	.org
		Other (please describe):
Date Received:	date: 5-17-07, amended on 6-26-2007	
Date Responded to (please mark column B with an X if still pending):	date:	
	<input checked="" type="checkbox"/>	Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/25b4.pdf	
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input checked="" type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
<input type="checkbox"/>	Changes, other than those requested were made (please describe below):	
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input checked="" type="checkbox"/>	Database: Complaint is that flaw
	<input type="checkbox"/>	Fact Sheet
	<input type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assesment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input checked="" type="checkbox"/>	Website
	<input checked="" type="checkbox"/>	Other (please describe below):
Has An Appeal been filed?	<input type="checkbox"/>	Yes
	<input checked="" type="checkbox"/>	No

If an Appeal on this request has been filed in FY07 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this appeal?	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY07.

Agency/SubAgency Receiving Correction Request	FDA
Agency Request Name or Number (if applicable):	Omega
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/22a.shtml
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual
	<input type="checkbox"/> Trade Group (.com)
	<input type="checkbox"/> Trade Group (.org)
	<input checked="" type="checkbox"/> Corporation: Omega Laboratories
	<input type="checkbox"/> Law Firm on behalf of:
	<input type="checkbox"/> Individual
	<input type="checkbox"/> .com <input type="checkbox"/> .org
	Other (please describe):
Date Received:	date: May 23, 2005
Date Responded to (please mark column B with an X if still pending):	date: January 18, 2007
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/22b8.pdf
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/> Still Pending
	<input type="checkbox"/> Full Correction
	<input type="checkbox"/> Partial Correction
	<input checked="" type="checkbox"/> No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below): Information removed from website pending review.
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure
	<input type="checkbox"/> Database
	<input type="checkbox"/> Fact Sheet
	<input type="checkbox"/> Report
	<input type="checkbox"/> Risk Assessment
	<input type="checkbox"/> Final Rule
	<input type="checkbox"/> Proposed Rule
	<input type="checkbox"/> Website
	<input type="checkbox"/> Other (please describe below): Letter to company that appears on FDA Website: http://www.fda.gov/cdrh/oivd/letters/120103-omega.html
Has An Appeal been filed?	<input checked="" type="checkbox"/> No

If an Appeal on this request has been filed in FY07 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this appeal?	Yes (if yest please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending Full Correction Partial Correction No Correction Disclaimer added to information on website Request was handled under a different process (please describe below): Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY07.

Agency/SubAgency Receiving Correction Request	FDA	
Agency Request Name or Number (if applicable):	Allergens Threshold Report	
Link to Correction Request:	http://aspe.hhs.gov/infoquality/request&response/31a.pdf	
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input checked="" type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	.com .org
	<input type="checkbox"/>	Other (please describe):
Date Received:	date: August 2, 2006	
Date Responded to (please mark column B with an X if still pending):	<input type="checkbox"/>	date: December 15, 2006
	<input type="checkbox"/>	Still pending
Link to Agency Response:	http://aspe.hhs.gov/infoquality/request&response/31b2.pdf	
Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input checked="" type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
	<input type="checkbox"/>	Changes, other than those requested were made (please describe below):
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input checked="" type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assesment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input type="checkbox"/>	Website
	<input type="checkbox"/>	Other (please describe below):
Has An Appeal been filed?	<input checked="" type="checkbox"/>	Yes
	<input type="checkbox"/>	No

If an Appeal on this request has been filed in FY07 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	http://aspe.hhs.gov/infoquality/request&response/31c1.pdf	
Date of Appeal request:	date: January 17, 2007	
Date Appeal Responded to (please mark column B with an X if still pending):	date: July 31, 2007	
	<input type="checkbox"/> Still pending	
Link to Appeal Response:	http://aspe.hhs.gov/infoquality/request&response/31d4.pdf	
Appeal Process used (please describe mechanism used in a few sentences):		
Is there any judicial review associated with this appeal?	Yes (if yes please describe):	
	<input checked="" type="checkbox"/>	No
Appeal Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Still Pending
	<input type="checkbox"/>	Full Correction
	<input type="checkbox"/>	Partial Correction
	<input checked="" type="checkbox"/>	No Correction
	<input type="checkbox"/>	Disclaimer added to information on website
	<input type="checkbox"/>	Request was handled under a different process (please describe below):
	<input type="checkbox"/>	Changes, other than those requested were made (please describe below):

Section III. Please fill out this form for EACH Correction Request (and associated Appeal Request) Received in FY07.

Agency/SubAgency Receiving Correction Request	
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Agency Request Name or Number (if applicable):	
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Link to Correction Request:	
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Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/>	Private Individual
	<input type="checkbox"/>	Trade Group (.com)
	<input type="checkbox"/>	Trade Group (.org)
	<input type="checkbox"/>	Corporation
	<input type="checkbox"/>	Law Firm on behalf of:
	<input type="checkbox"/>	Individual
	<input type="checkbox"/>	.com
<input type="checkbox"/>	.org	
<input type="checkbox"/>	Other (please describe):	

Date Received:	date:	
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Date Responded to (please mark column B with an X if still pending):	date:	
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Link to Agency Response:	
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Request Resolution (please mark appropriate choice with an X in column B describing how the agency handled the request):	<input type="checkbox"/>	Still Pending	
	<input type="checkbox"/>	Full Correction	
	<input type="checkbox"/>	Partial Correction	
	<input type="checkbox"/>	No Correction	
	<input type="checkbox"/>	Disclaimer added to information on website	
	<input type="checkbox"/>	Request was handled under a different process (please describe below):	
	<input type="checkbox"/>	Changes, other than those requested were made (please describe below):	

Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/>	Brochure
	<input type="checkbox"/>	Database
	<input type="checkbox"/>	Fact Sheet
	<input type="checkbox"/>	Report
	<input type="checkbox"/>	Risk Assessment
	<input type="checkbox"/>	Final Rule
	<input type="checkbox"/>	Proposed Rule
	<input type="checkbox"/>	Website
	<input type="checkbox"/>	Other (please describe below):

Has An Appeal been filed?	<input type="checkbox"/>	Yes
	<input type="checkbox"/>	No

If an Appeal on this request has been filed in FY07 you must fill out the rest of this form (otherwise leave blank):

Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this appeal?	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending
	Full Correction
	Partial Correction
	No Correction
	Disclaimer added to information on website
	Request was handled under a different process (please describe below):
	Changes, other than those requested were made (please describe below):

Section IV. Please fill out this form for EACH Outstanding Correction Request from FY03, FY04, FY05, or FY06 which was completed in FY07 or is still pending. If an Appeal has been filed in FY07 on an FY03, FY04, FY05, or FY06 request you must include description of the correction request and appeal.

Agency/Sub Agency Receiving Correction Request	Department of Health and Human Services (DHHS), National Institutes of Health (NIH), National Institute of Environmental Sciences (NIEHS), National Toxicology Program (NTP)	
Agency Request Name or Number (if applicable)		
Link to Correction Request	http://aspe.hhs.gov/infoquality/requests.shtml (#28)	
Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual	
	<input type="checkbox"/> Trade Group (.com)	
	<input type="checkbox"/> Trade Group (.org)	
	<input checked="" type="checkbox"/> Corporation	Chemical Products Corporation (CPC)
	<input type="checkbox"/> Law Firm on behalf of:	
	<input type="checkbox"/> Individual	
	<input type="checkbox"/> .com	
	<input type="checkbox"/> .org	
	Other (please describe):	
Date Received:	date: June 6, 2006 (addendums received on July 20, 2006, July 26, 2006, and October 31,	
Date Responded to (please mark column B with an X if still pending):	date: December 22, 2006	
Link to Agency Response:	http://aspe.hhs.gov/infoquality/requests.shtml (#28)	
Request Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Requests was handled by senior NTP staff	
	<input type="checkbox"/>	
	<input type="checkbox"/> Disclaimer added to information on website	
	<input type="checkbox"/> Request was handled under a different process (please describe below):	
	Changes, other than those requested were made (please describe below):	
Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure	
	<input type="checkbox"/> Database	
	<input type="checkbox"/> Fact Sheet	
	<input type="checkbox"/> Report	The requestor asks that the NTP Technical Report 494, NIH Publication No. 05-3953, be withdrawn because of factual errors.
	<input type="checkbox"/> Risk Assessment	
	<input type="checkbox"/> Final Rule	
	<input type="checkbox"/> Proposed Rule	
	<input type="checkbox"/> Website	
	Other (please describe below):	
	Description of Requested Correction: The requests asks that NTP Technical Report 494 be withdrawn because the conclusions presented in the report were accepted by NTP's Board of Scientific Counselors Technical Reports Review Subcommittee based upon undocumented genetic toxicology data presented for the first time at the meeting on December 9, 2004 and subsequently incorporated into TR494. The amended complaint dated July 13 questions information about the purity of the anthraquinone reported in TR494 and provided by an NTP staff to the Subcommittee at its meeting and reported in the minutes. The amended complaint of July 17 questions the storage conditions reported for anthraquinone in TR494. The addendum of October 31 was mutagenicity data on anthraquinone from Zenica Specialties for inclusion in the IUCLID dataset	

Has An Appeal been filed?	Yes	X
	No	
If an Appeal has been filed in FY07 on an FY03, FY04, FY05, or FY06 request you must fill out the rest of this form (otherwise leave blank):		
Link to Appeal Request:	#28	
Date of Appeal request:	January 5, 2007 (addendum provided November 2, 2007 at a meeting with HHS, NIH, OMB, and NIEHS, Mr. Cook and CPC)	
Date Appeal Responded to (please mark column B with an X if still pending):	date:	Still pending X
Link to Appeal Response:		
Appeal Process used (please describe mechanism used in a few sentences):	Appeal being handled by senior NIEHS staff.	
Is there any judicial review associated with this	Yes (if yes please describe):	No X
Appeal Resolution (please mark appropriate choice with an X in column B):	Still Pending	
	Full Correction	
	Partial Correction	
	No Correction	
	Disclaimer added to information on website	
	Request was handled under a different process (please describe below):	
	Changes, other than those requested were made (please describe below):	
Description of Request: The requestor appeals the NTP's decision regarding withdrawal of NTP Technical Report TR 494.		

Section IV. Please fill out this form for EACH Outstanding Correction Request from FY03, FY04, FY05, or FY06 which was completed in FY07 or is still pending. If an Appeal has been filed in FY07 on an FY03, FY04, FY05, or FY06 request you must include description of the correction request and appeal.

Agency/Sub Agency Receiving Correction Request	
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Agency Request Name or Number (if applicable):	
--	--

Link to Correction Request:	
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Requestor Affiliation (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Private Individual <input type="checkbox"/> Trade Group (.com) <input type="checkbox"/> Trade Group (.org) <input type="checkbox"/> Corporation <input type="checkbox"/> Law Firm on behalf of: <input type="checkbox"/> Individual <input type="checkbox"/> .com <input type="checkbox"/> .org <input type="checkbox"/> Other (please describe):
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Date Received:	date:
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Date Responded to (please mark column B with an X if still pending):	date:	<input type="checkbox"/> Still pending
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Link to Agency Response:	
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Request Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Still Pending <input type="checkbox"/> Full Correction <input type="checkbox"/> Partial Correction <input type="checkbox"/> No Correction <input type="checkbox"/> Disclaimer added to information on website <input type="checkbox"/> Request was handled under a different process (please describe below): <input type="checkbox"/> Changes, other than those requested were made (please describe below):
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Information requested to be changed is found in (mark column B with an X for all that apply):	<input type="checkbox"/> Brochure <input type="checkbox"/> Database <input type="checkbox"/> Fact Sheet <input type="checkbox"/> Report <input type="checkbox"/> Risk Assessment <input type="checkbox"/> Final Rule <input type="checkbox"/> Proposed Rule <input type="checkbox"/> Website <input type="checkbox"/> Other (please describe below): Background material for Committee
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Has An Appeal been filed?	Yes
	No
If an Appeal has been filed in FY07 on an FY03, FY04, FY05, or FY06 request you must fill out the rest of this form (otherwise leave blank):	
Link to Appeal Request:	
Date of Appeal request:	date:
Date Appeal Responded to (please mark column B with an X if still pending):	date: Still pending
Link to Appeal Response:	
Appeal Process used (please describe mechanism used in a few sentences):	
Is there any judicial review associated with this	Yes (if yes please describe): No
Appeal Resolution (please mark appropriate choice with an X in column B):	<input type="checkbox"/> Still Pending <input type="checkbox"/> Full Correction <input type="checkbox"/> Partial Correction <input type="checkbox"/> No Correction <input type="checkbox"/> Disclaimer added to information on website <input type="checkbox"/> Request was handled under a different process (please describe below): <input type="checkbox"/> Changes, other than those requested were made (please describe below):
Summary of Request:	