

FREEDOM OF INFORMATION ACT REQUEST

By Facsimile/ Hard Copy to follow

April 6, 2005

Freedom of Information Staff
FDA
5600 Fishers Lane
Room 12A-30
Rockville, MD 20857
Fax: (301) 443-1726

Dear Freedom of Information Staff:

Friends of the Earth ("FoE") requests records, regardless of format, medium, or physical characteristics, and including electronic records and information, audiotapes, videotapes and photographs, pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. §§ 552 et seq and the Food and Drug Administration's implementing regulations, 21 C.F.R. Part 20.

I. Records Requested

This request relates to a survey conducted by the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Cosmetics and Colors (OCAC) of cosmetic products to determine the contribution of phthalates to human exposure. This survey was mentioned as item #51 in Enclosure 1 of the "*CFSAN 2004 Program Priorities Accomplishments through June 2004*" which can be found at <http://www.cfsan.fda.gov/~dms/cfsan804.html#summary>. According to this report, the OCAC "Conducted a survey of products to determine the contribution of phthalates to human exposure. CFSAN's Office of Cosmetics and Colors (OCAC) surveyed 48 cosmetic products and identified 5 phthalate esters in 32 of the products. Phthalate levels ranging from 16 ppm to 59,000 ppm were found; the highest levels found were in nail enamels."

Please produce:

- A copy of the full survey, full survey results (including product names and brand names of all products tested), scientific data, testing procedure and other documents related to the aforementioned survey of products to determine the contribution of phthalates to human exposure conducted by CFSAN's Office of Cosmetics and Colors (OCAC).

Please search for responsive records regardless of format, medium, or physical characteristics. Please include briefing papers, descriptions of research methods and procedures, meeting notes, memorandum or correspondence related to this survey and its results. We seek records of any kind, including electronic records, audiotapes, videotapes and photographs.

There is no basis for claiming that the records requested herein are exempt from immediate disclosure under FOIA. Each of these records is described by 5 U.S.C. §552(a)(2) as information an agency is required to make available to the public and the United States Attorney

General has indicated that the Justice Department will only defend a decision not to disclose documents where a "sound legal basis" for non-disclosure exists. Memorandum from Attorney General John Ashcroft to Heads of Departments and Agencies on the Freedom of Information Act, October 12, 2001.

If, however, it is your position that any portion of the requested records is exempt from disclosure, FoE requests that you provide it with an index of those documents as required under Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974). A Vaughn index must describe each document claimed as exempt with sufficient specificity "to permit a reasoned judgment as to whether the material is actually exempt under FOIA." Founding Church of Scientology v. Bell, 603 F.2d 945, 949 (D.C. Cir. 1979). Moreover, the Vaughn index must "describe each document or portion thereof withheld, and for each withholding it must discuss the consequences of supplying the sought-after information." King v. U.S. Dep't of Justice, 830 F.2d 210, 223-24 (D.C. Cir. 1987). Further, "the withholding agency must supply 'a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply.'" Id. at 224 (citing Mead Data Central v. U.S. Dept. of the Air Force, 566 F.2d 242, 251 (D.C. Cir. 1977)).

In the event that some portions of the requested documents are properly exempt from disclosure, please disclose any reasonably segregable nonexempt portions of the requested documents. *See* 5 U.S.C. § 552(b) ("Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt. . ."); *see also* Schiller v. National Labor Relations Board, 964 F.2d 1205, 1209 (D.C. Cir. 1992); 15 C.F.R. §4.6. If it is your position that a document contains non-exempt segments but that those non-exempt segments are so dispersed throughout the document as to make segregation impossible, please state what portion of the document is non-exempt and how the material is dispersed throughout the document. Mead Data Central, 566 F.2d at 261. Claims of nonsegregability must be made with the same degree of detail as required for claims of exemptions in a Vaughn index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

Fee Waiver Request

FoE further requests that FDA waive all charges for search and review associated with this request, as provided by 5 U.S.C. § 552(a)(4)(A)(iii) and Food and Drug Administration regulations, 21 C.F.R. 20.43. FoE satisfies both tests for a waiver of fees under FDA's regulations. However, in the event that FDA deems that Friends of the Earth does not qualify for a complete fee waiver, Friends of the Earth is willing to pay up to \$100 in fees associated with fulfilling our Freedom of Information Act request.

Public Interest

The disclosure of the information requested by FoE's request will advance the understanding of the general public as distinguished from a "narrow segment of interested persons". FoE is a national environmental organization, dedicated to preserving the health and diversity of the planet and empowering citizens to have an influential voice in decisions affecting their

environment and their health. The subject matter of the requested records concerns the operations or activities of the federal government and is likely to contribute to a greater public understanding of federal government operations or activities. Specifically, these records are likely to contribute to the public's understanding the government's role and actions related to sources of human exposure to phthalates, chemicals that have been linked to public health harms and of great interest to the public in recent years.

FoE has already proven its intention and ability to disseminate widely related information that the organization obtains pursuant to requests such as this one. In fact, as a public policy research and environmental organization, FoE routinely employs a host of methods to publicly release information received through FOIA requests. The means of distribution include websites (www.foe.org) and (www.safecosmetics.org), regular email updates to our membership and activists, our Friends of the Earth Magazine, press releases, and press conferences. FoE and our allies' (Breast Cancer Fund, Environmental Working Group and others) work on these issues has been covered by the *Wall Street Journal*, the *San Francisco Chronicle* and *The Nation*. FoE intends to use one or more of these means to educate the public about the survey conducted by the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Cosmetics and Colors (OCAC) of cosmetic products to determine the contribution of phthalates to human exposure. Production of the requested records to FoE would thus bring enhanced understanding of an important government activity and information on products containing a chemical of concern to the public at large that is not accessible to the public via other means.

Moreover, the request is for non-commercial purposes. FoE is a registered §501(C)(3) Corporation, and the release of the requested information is not in FoE's commercial interest. FoE will analyze the information responsive to this request, and will likely share its analysis with its members and the public either through memorandums or reports, often made available on the Internet site: <http://www.foe.org/>. Under these circumstances, Friends of the Earth fully satisfies the criteria for a fee waiver.

Conclusion

Please respond to this request in writing within twenty (20) days as required under 5 U.S.C. §552(a)(6)(A)(I). If all of the requested documents are not available within that time period, Friends of the Earth requests that you provide it with all requested documents or portions of documents which are available within that time period. If you have any questions about this request or foresee problems in fully releasing the requested records within the twenty day period, please call us within that time period. We can be reached at (202) 222-0712. Please send copies of the requested documents to Lisa Archer, Friends of the Earth, 1717 Massachusetts Ave, NW, Suite 600, Washington, D.C. 20036.

Sincerely,



Lisa Archer
Friends of the Earth

Cc:
Robert E. Brackett, Ph.D.
Director
Center for Food Safety and Applied Nutrition

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)