

remains the uniform executive branch report form for most of those executive branch employees who are required by their agencies to report confidentially on their financial interests. The OGE Form 450 is to be filed by each reporting individual with the designated agency ethics official at the executive department or agency where he or she is or will be employed.

Reporting individuals are regular employees whose positions have been designated by their agency under 5 CFR part 2634.904 as requiring confidential financial disclosure in order to help avoid conflicts with their assigned responsibilities; additionally, all special Government employees (SGE) are generally required to file. Agencies may, if appropriate under the OGE regulation, exclude certain regular employees or SGEs as provided in 5 CFR 2634.905. Reports are normally required to be filed within 30 days of entering a covered position (or earlier if required by the agency concerned), and again annually in the fall if the employee serves for more than 60 days in the position. As indicated in § 2634.907 of the OGE regulation, the information required to be collected includes assets and sources of income, liabilities, outside positions, employment agreements and arrangements, and gifts and travel reimbursements, subject to certain thresholds and exclusions.

Most of the persons who file this report form are current executive branch Government employees at the time they complete the forms. However, some filers are private citizens who are asked by their prospective agency to file a new entrant report prior to entering Government service in order to permit advance checking for any potential conflicts of interest and resolution thereof by agreement to recuse or divest, obtaining of a waiver, etc. Based on OGE's annual agency ethics program questionnaire responses for 1996 and 1997, OGE estimates that an average of approximately 281,500 OGE 450 report forms will be filed each year for the next three years throughout the executive branch. This estimate is based on the average number of forms filed branchwide for the past two years, some 286,450 in 1996 and 276,444 in 1997, for a total of 562,894, with that number then divided in half and rounded. Of these, OGE estimates that no more than between 5% and 10%, or some 14,075 to 28,150 per year at most, will be filed by private citizens, those potential (incoming) regular employees whose positions are designated for confidential disclosure filing as well as potential special Government employees whose agencies require that they file their new

entrant reports prior to assuming Government responsibilities. No termination reports are required.

Each filing is estimated to take an average of one and one-half hours. The number of private citizens whose reports are filed each year with OGE is less than 10, but pursuant to 5 CFR 1320.3(c)(4)(i), the lower limit for this general regulatory-based requirement is set at 10 private persons (OGE-processed reports). This yields an annual reporting burden of 15 hours, the same as in OGE's current OMB inventory for this information collection. The remainder of the private citizen reports are filed with other departments and agencies throughout the executive branch.

Public comment is invited on the proposed slightly revised OGE Form 450 as set forth in this notice, including specifically views on the need for and practical utility of this proposed modified collection of information, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology).

Comments received in response to this notice will be summarized for, and may be included with, OGE's future request for OMB paperwork approval for the proposed slightly revised OGE Form 450. At that time, OGE will publish a second paperwork notice in the **Federal Register** to inform the agencies and the public.

Approved: October 15, 1998.

Stephen D. Potts,

Director, Office of Government Ethics.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR-137]

Availability of Draft Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA),

Section 104(i)(3) [42 U.S.C. 9604(i)(3)] directs the Administrator of ATSDR to prepare toxicological profiles of priority hazardous substances and to revise and publish each updated toxicological profile as necessary. This notice announces the availability of the 12th set of toxicological profiles, one being a new draft and five updated drafts, prepared by ATSDR for review and comment.

DATES: In order to be considered, comments on these draft toxicological profiles must be received on or before February 22, 1999. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

ADDRESSES: Requests for copies of the draft toxicological profiles should be sent to the attention of Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333. Comments regarding the draft toxicological profiles should be sent to the attention of Dr. Ganga Choudhary, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR-137. Send one copy of all comments and three copies of all supporting documents to Dr. Ganga Choudhary at the above stated address by the end of the comment period. Because all public comments regarding ATSDR toxicological profiles are available for public inspection [after the profile is published in final], no confidential business information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Norman, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-6322.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99-499) amends the Comprehensive

Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 et seq.) by establishing certain responsibilities for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these responsibilities is that the Administrator of ATSDR prepare toxicological profiles for substances included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on November 17, 1997 (62 FR 61332). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); and April 29, 1996 (61 FR 18744). [CERCLA also requires ATSDR to assure the initiation of a research program to fill data needs associated with the substances.]

Section 104(i)(3) of CERCLA [42 U.S.C. 9604(i)(3)] outlines the content of these profiles. Each profile will include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and these data are to be used to identify the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 1998.

Docu- ment	Hazardous sub- stance	CAS No.
1	Arsenic	007440-38-2
	Dimethylarsenic Acid.	000075-60-5
2	Chromium	007440-47-3
	Chromium, Hexavalent.	018540-29-9
		007789-09-5
		013765-19-0
		001333-82-0
		007758-97-6
		007789-00-6
		007778-50-9
		007775-11-3
		007789-06-2
		013530-65-9
3	Endosulfan	000115-29-7
	Endosulfan, alpha	000959-98-8
	Endosulfan, sulfate	001031-07-8
	Endosulfan, beta ..	033213-65-9
4	Ethion	000563-12-2
5	Methylene Chloride	000075-09-2
6	Toluene	000108-88-3

All profiles issued as "Drafts for Public Comment" represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 15, 1998.

Donna Garland,

Acting Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0143]

Agency Emergency Processing Request Under OMB Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns procedures recommended in a guidance entitled

"Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV."

DATES: Submit written comments on the collection of information by November 2, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance entitled "Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and