

Dated: April 1, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Community/Tribal Subcommittee and the Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following subcommittee and committee meetings.

Name: Community/Tribal Subcommittee.

Times and Dates: 1:30 p.m.-5 p.m., April 28, 1998. 8:30 a.m.-5 p.m., April 29, 1998.

Place: ATSDR, 35 Executive Park Drive, Training Room, Atlanta, Georgia 30329, telephone 404/639-0708.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 60 people.

Purpose: This subcommittee will bring to the Board advice, citizen input, and recommendations on community and tribal programs, practices, and policies of the Agency.

Matters to be Discussed: Agenda items include identifying issues and concerns of the Subcommittee related to ATSDR community and tribal programs, policies, and activities. Recommendations will be developed and a report will be presented to the Board.

Name: Board of Scientific Counselors, ATSDR.

Times and Dates: 8:30 a.m.-5 p.m., April 30, 1998. 8:30 a.m.-3:45 p.m., May 1, 1998.

Place: ATSDR, 35 Executive Park Drive, Training Room, Atlanta, Georgia 30329, telephone 404/639-0708.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 60 people.

Purpose: The Board of Scientific Counselors, ATSDR, advises the Secretary; the Assistant Secretary for Health; and the Administrator, ATSDR, on ATSDR programs to ensure scientific quality, timeliness, utility, and dissemination of results. Specifically, the Board advises on the adequacy of science in ATSDR-supported research, emerging problems that require scientific investigation, accuracy and currency of the science in ATSDR reports, and program areas to emphasize and/or to de-emphasize. In addition, the Board recommends research programs and conference support for which the Agency seeks to make grants to universities, colleges,

research institutions, hospitals, and other public and private organizations.

Matters to be Discussed: Agenda items will include a report from the Community/Tribal Subcommittee on issues and concerns related to hazardous waste sites; a report on the TCE speech and hearing study; a report by the external evaluation panel on the ATSDR Program of Research for Historically Black Colleges and Universities; workgroup reports on the Great Lakes Health Effects Research Program and Uncertainty in Health Guidance Values; a report of findings and public health implications of the Agency's Hazardous Substances Emergency Events Surveillance; and updates on the Environmental Cancer Registry and the Mississippi Delta Project Needs Assessment Profiles.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information:

Charles Xintaras, Sc.D., Executive Secretary, BSC, ATSDR, M/S E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0708.

Dated: April 1, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0192]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 purpose of the proposed collection of information is to enable manufacturers of biological products to use specific establishment and product license application (PLA) forms in submissions seeking FDA approval of their products.

DATES: Submit written comments on the collection of information by April 20, 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: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13 because the information is essential to the agency's mission. The agency cannot reasonably comply with the normal clearance provisions of the PRA of 1995 because the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of 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.

Establishment and Product License Applications: Forms FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314—21 CFR 601.2 and 601.12—(OMB Control Number 0910-0124—Reinstatement)

FDA is the Federal agency charged with responsibility for insuring the safety and effectiveness of drugs and the safety, purity, and potency of biological products. Manufacturers of biological products for human use must file an application for FDA approval of the product prior to introducing it into interstate commerce. The information provided by manufacturers on these license application forms is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that biologics for human use have been shown to be safe, pure, and potent. The uniform format of the forms provides for orderly, efficient review by