

organization, functions and delegations of authority for the Office for Human Research Protections is March 18, 2002.

Dated: February 28, 2002.

**Eve E. Slater,**

*Assistant Secretary for Health.*

[FR Doc. 02-5303 Filed 3-5-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

#### Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Oak Ridge Reservation Health Effects Subcommittee

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) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Oak Ridge Reservation Health Effects Subcommittee (ORRHES).

*Time and Date:* 12 p.m.—8 p.m., March 26, 2002.

*Place:* YWCA of Oak Ridge, 1660 Oak Ridge Turnpike, Oak Ridge, Tennessee, 37830. Telephone: (865) 482-2008.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

*Background:* A Memorandum of Understanding (MOU) signed in October 1990 and renewed in September 2000 between ATSDR and DOE, delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles. In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 2000, the Department of Health and Human Services (HHS) has been given

the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

*Purpose:* This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing the public with a vehicle to express concerns and provide advice and recommendations to CDC and ATSDR. The purpose of this meeting is to receive updates from ATSDR and CDC, and to address other issues and topics, as necessary.

*Matters To Be Discussed:* The agenda includes a discussion of the public health assessment process, updates from the Public Health Assessment, Health Needs Assessment, Agenda, and Outreach and Communications Workgroup. Agenda items are subject to change as priorities dictate.

**FOR MORE INFORMATION CONTACT:** La Freta Dalton, Designated Federal Official, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E-54, Atlanta, Georgia 30333, telephone 1-888-42-ATSDR(28737), fax 404/498-1744.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 27, 2002.

**Alvin Hall,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Committee on Childhood Lead Poisoning Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

*Name:* Advisory Committee on Childhood Lead Poisoning Prevention.

*Time and Date:* 8:30 a.m.—5:00 p.m., March 12, 2002.

*Place:* Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202, telephone 410/539-2000.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 90 people.

*Purpose:* The Committee shall provide advice and guidance to the Secretary; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The Committee shall also review and report regularly on childhood lead poisoning prevention practices and recommend improvements in national childhood lead poisoning prevention efforts.

*Matters to be Discussed:* Agenda items include: Updates on Primary Prevention issues, Medicaid Targeted Screening issues, and Discussions on Future of Lead Poisoning Prevention Research, Revision of Adopted Children Letter, and Recent International Lead Activities by CDC's Lead Poisoning Prevention Branch. Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

*Contact Person for More Information:* Gary Noonan, Acting Chief, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, NE, M/S E-25, Atlanta, Georgia 30333, telephone 404/498-1442, fax 404/498-1444.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the

Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 27, 2002.

**Alvin Hall,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0055]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Recall Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements related to the recall of infant formula.

**DATES:** Submit written or electronic comments on the collection of information by May 6, 2002.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280 (OMB Control No. 0910-0188)—Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation

prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with an FDA approved notice of recall. Section 107.240 requires the recalling firm to: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelflife of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA's ability to ensure that recalls are conducted properly would be greatly impaired.

FDA estimates the burden of this collection of information as follows: