

**Charles Gollmar,**

*Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering and Environmental Laboratory 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: Idaho National Engineering and Environmental Laboratory (INEEL) Health Effects Subcommittee.

*Times and Dates:* 8:30 a.m.-5:30 p.m., April 7, 1998; 7 p.m.-8 p.m., April 7, 1998; 7:30 a.m.-4 p.m., April 8, 1998.

*Place:* DoubleTree Hotel, 2900 Chinden Boulevard, Boise, Idaho 83714, telephone 208/343-1871, fax 208/344-1079.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

#### Background

Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) was 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 use. HHS delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU 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.

#### Purpose

This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

#### Matters To Be Discussed

Agenda items include presentations from the CDC and the U.S. Department of Energy on national priorities and research agendas; the National Institute for Occupational Safety and Health will provide updates on the progress of current studies; the National Cancer Institute (NCI) will update the NCI study, and Fallout and Thyroid Cancer; the Radiological Assessments Corporation will provide updates on the

Status of Chemical Screening and Radionuclide Screening; and committee deliberations and working group discussions. On April 7, at 7 p.m., the meeting will continue in order to allow more time for public input and comment.

Agenda items are subject to change as priorities dictate.

*Contact Persons for More Information:* Arthur J. Robinson, Jr., or Sharona Woodley, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE (F-35), Atlanta, Georgia 30341-3724, telephone 770/488-7040, FAX 770/488-7044.

Dated: March 17, 1998.

#### Carolyn J. Russell,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Application and program reporting requirements for the Children's Justice Act authorized by the Child Abuse Prevention and Treatment Act (as amended).

*OMB No.:* 0980-0196.

*Description:* Application information is required when a State wishes to be considered for a Children's justice Act grant award. Program reports are used by Children's Bureau and the States as a mechanism for monitoring, evaluating and measuring State achievements in addressing the problems of child abuse and neglect. State reports also provide information for the Congress.

*Respondents:* Individuals and Households; Not-for-Profit Institutions; and State, Local or Tribal Govt.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application .....	52	1	40	2,080
Performance Report .....	52	1	20	1,040

*Estimated Total Annual Burden Hours:* 3,120

*Additional Information:* Copies of the proposed collection may be obtained by writing to The Administration for

Children and Families, Office of Information Services, Division of Information Resource Management

Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Ms. Wendy Taylor.

Dated: March 17, 1998.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0157]

#### 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 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's food labeling regulations.

**DATES:** Submit written comments on the collection of information by May 22, 1998.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management

(HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1223.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

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.

#### Food Labeling Regulations (21 CFR Parts 101, 102, 104, and 105)

FDA regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to FDA. FDA's food labeling regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the FPLA) (15 U.S.C. 1453, 1454, and 1455) and of sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food,

Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the act and the FPLA. The purpose of this notice is to consolidate all of the information collection provisions in these regulations into one notice for public comment under the PRA.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.9(g)(9) also provides for the submission to FDA of requests for alternative approaches to nutrition labeling. Finally, § 101.9(j)(18) provides for the submission to FDA of notices from firms claiming the small business exemption from nutrition labeling.

Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show FDA detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g)