

other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo 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 National Center for Environmental Health (NCEH) and the National Institute for Occupational Safety and Health (NIOSH) regarding the progress of current studies. There will also be a preliminary Public Health Assessment report for the Fernald area from the Agency for Toxic Substances and Chemical Registry (ATSDR).

Agenda items are subject to change as priorities dictate.

Contact Persons For More Information: Dr. David Pedersen, Health-Related Energy Research Branch, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, CDC, Robert A. Taft Laboratory, 4676 Columbia Parkway, M/S R-44, Cincinnati, Ohio 45226. Telephone 513/841-4400, Fax 513/841-4470.

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: August 10, 1999.

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

Proposed Information Collection Activity; Comment Request

Proposed Project:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Leveraging Report	70	1	38	2,660

Estimated Total Annual Burden Hours: 2,660.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and

Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

Title: Low Income Home Energy Assistance Program (LIHEAP) Leveraging Report.

OMB No.: 0970-0121.

Description: The LIHEAP leveraging incentive program rewards LIHEAP grantees that have leveraged nonfederal home energy resources for low income households. The LIHEAP leveraging report is the application for leveraging incentive funds that these LIHEAP grantees submit to HHS for each fiscal year in which they leverage countable resources. Participation in the leveraging incentive program is voluntary.

The Leveraging report obtains information on the resources leveraged by LIHEAP grantees each fiscal year (as cash, discounts, waivers, and in-kind); the benefits provided to low income households by these resources (for example, as fuel and payments for fuel, as home heating and cooling equipment, and as weatherization materials and installation); and the fair market value of these resources/benefits. HHS needs this information in order to carry out statutory requirements for administering the LIHEAP leveraging incentive program, to determine countability and valuation of grantees' leveraged nonfederal home energy resources, and to determine grantees' shares of leveraging incentive funds. HHS proposes to request a 3-year extension of OMB approval for the currently approved LIHEAP leveraging report information collection.

Respondents: State and Tribal Governments.

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 10, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2695]

Agency Emergency Processing Under OMB Review; Survey of Biomedical Equipment Manufacturers for Year 2000 Compliance

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, originally approved under OMB control number 0900-0003, concerns a survey of manufacturers of biomedical equipment about the Year 2000 (Y2K) compliance of their products.

DATES: Submit written comments on the collection of information by August 19, 1999.

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: Thomas B. Shope, Office of Science and Technology (HFZ-140), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-3314, ext. 132, or FAX 301-443-9101.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information

under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This collection is needed immediately because some manufacturers have not yet provided data on their noncompliant products and because other manufacturers have provided either incomplete or preliminary, not final, information. Health care facilities and others are depending upon the information in the FDA-operated Federal Y2K Biomedical Equipment Clearinghouse (the Clearinghouse) as they assess the Y2K compliance of the biomedical equipment used in their facilities. In order to continue this collection activity, it is necessary to extend this activity until February 29, 2000. FDA is requesting OMB approval by August 19, 1999.

- 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.

Title: Survey of Biomedical Equipment Manufacturers for Year 2000 Compliance

The Deputy Secretary of the Department of Health and Human Services, on behalf of the governmentwide Biomedical Equipment Subgroup of the Chief Information Officer Council's Y2K Subcommittee, is surveying manufacturers of biomedical equipment about the Y2K compliance of their products. The existence of a Y2K date problem in biomedical equipment could pose potentially serious health and safety consequences.

Manufacturers have been asked to post information about noncompliant products on a website and link this to a government website on biomedical equipment. If all of a manufacturer's products are compliant, they may

provide a notice of total product compliance. Manufacturers have the option to mail the information to the Department of Health and Human Services (DHHS) for posting on the government website, or they may provide it electronically. All information collected is available to the public through the government website.

FDA, on behalf of DHHS, is continuing to solicit product status information from manufacturers that have not responded to this request and to seek clarification or expansion of specific information that has been received, but is incomplete.

- To be Y2K compliant, a product must be able to accurately process date information in the Y2K and between the 20th and 21st centuries, including leap year calculations. Medical devices and scientific laboratory equipment may experience problems beginning January 1, 2000, if the computer systems, software applications, or embedded chips used in these devices and equipment contain two-digit fields for year representation.

FDA regulates medical devices and needs information regarding the Y2K compliance of these products. Under a previous good manufacturing practices regulation and the current quality system regulation, effective June 1, 1997, manufacturers must investigate and correct problems with medical devices that present a significant risk to public health. This includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Also, section 518 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h) requires notification of users or purchasers when a device presents an unreasonable risk of substantial harm to public health. These regulations, however, do not apply to all biomedical equipment, such as scientific laboratory equipment, but only to medical devices. Therefore, a proactive collection of Y2K compliance information of all biomedical equipment is necessary to prevent a Y2K date problem from causing any public health risk in the patient care services and health research initiatives of the next century.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
450	1	450	8	3,600

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.