

distribution of cardiovascular diseases with particular emphasis on priority populations; identifies trends in mortality and risk factors; identifies barriers to successful program implementation; and describes existing policy and environmental influences in terms of their affect on public awareness and the risk factors for cardiovascular diseases.

b. Staffing (10 Points)

The degree to which the proposed staff have the relevant background, qualifications, and experience; the degree to which the organizational structure supports staffs' ability to conduct proposed activities; the degree of staff coordination between relevant program within the State health department.

c. Comprehensive Work Plan (45 Points)

(1)(20 Points) The extent to which the work plan for achieving the proposed activities appears realistic and feasible and relates to the stated program requirements and purposes of this cooperative agreement. The extent to which the plan addresses the needs of the State, the feasibility of the plan and the appropriateness of the planned interventions to the cardiovascular disease problem, and the adequacy of the plan to identify and address the needs of priority populations.

(2) (20 Points) The extent to which the work plan addresses the problem through policy and environmental strategies and other appropriate population-based approaches and the extent of program activities that appropriately use settings (*e.g.*, worksites, the media, schools, community-based organizations, faith-based organizations, the community at large).

(3) (5 Points) The extent to which collaboration of State nutrition, physical activity, tobacco, health promotion, and other chronic disease programs with external partners is used to deliver the program; the extent to which coordination with other State chronic disease programs and other State agencies enhances the cardiovascular disease program; and the extent of involvement of community-based organizations in the implementation of the program.

d. Objectives (5 Points)

The degree to which the objectives are specific, time-phased, measurable, realistic, and relate to identified needs and purposes of the program, for both the general population as well as the targeted populations.

e. Evaluation (10 Points)

The extent to which the evaluation plan appears capable of monitoring progress toward meeting specific project objectives, assessing the impact of the program on the general population, assessing changes in the Priority populations, monitoring utilization of secondary prevention strategies, and assessing the implementation of policy and environmental strategies.

f. Budget (Not Scored)

The extent to which the budget appears reasonable and consistent with the proposed activities and intent of the program. For the Comprehensive application, matching funds should be listed on question 15 (estimated funding) of the application face page and section C of the Budget Information worksheet.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of the following:

1. Progress reports (semiannual);
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment II in the application kit.

- AR-7 Executive Order 12372 Review
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

**I. Authority and Catalog of Federal Domestic Assistance Number (CFDA)**

This program is authorized under sections 301(a) and 317b(k)(2) of the Public Health Service (PHS) Act, [42 U.S.C. sections 241(a) and 247b(k)(2)], as amended.

The Catalog of Federal Domestic Assistance (CFDA) number is 93.945.

**J. Where To Obtain Additional Information**

This and other CDC announcements can be found on the CDC home page at Internet address <http://www.cdc.gov>. Click on Funding then click on Grants and Cooperative Agreements.

If you have questions after reviewing the contents of all documents, business

management assistance may be obtained from: Van A. King, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00091, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone Number (770) 488-2751, Email address [vbk5@cdc.gov](mailto:vbk5@cdc.gov).

For program technical assistance, contact: Nancy B. Watkins, Division of Adult and Community Health National, Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, MS K-47, Atlanta, Georgia 30341-4146, Telephone Number (770) 488-8004, Email address [naw1@cdc.gov](mailto:naw1@cdc.gov).

Dated: May 22, 2000.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

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

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 Public Health Service Activities and Research at DOE Sites: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES).

*Times and Dates:* 8:30 a.m.-5 p.m., June 13, 2000. 8:30 a.m.-12:30 p.m., June 14, 2000.

*Place:* Coeur d'Alene Hotel, 115 South Second Street, Coeur d'Alene Idaho 83814, telephone 208/765-4000, fax 208/664-7678.

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

*Background:* Under a Memorandum of Understanding (MOU) signed in December 1990 with the Department of Energy (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 has 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 concerns to be expressed as advice and recommendations to CDC and ATSDR.

*Matters To Be Discussed:* Agenda items include an update on Pit 9 work; an update from the Risk Assessment Corporation (RAC); a report on the January 2000 National Cancer Institute workshop held in Rockville, Maryland on the health effects of I-131 related to Nevada Test Site fallout; and an update on the Evaluation Work Group project.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Arthur J. Robinson, Jr., Executive Secretary, INEELHES, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F-35, Atlanta, Georgia 30341-3724, telephone 770/488-7040, fax 770/488-7044.

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 CDC and ATSDR.

Dated: May 19, 2000.

**Julia M. Fuller,**

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

[FR Doc. 00-13130 Filed 5-25-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96M-0311]

#### 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 the collection of information contained in the Public Health Service (PHS) guideline entitled "PHS Guideline on Infectious Disease Issues in Xenotransplantation."

**DATES:** Submit written comments on the collection of information by July 25, 2002.

**ADDRESSES:** Submit written requests for single copies of the guideline entitled "PHS Guideline on Infectious Disease Issues in Xenotransplantation" to the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

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:

Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

#### SUPPLEMENTARY INFORMATION:

### I. Background

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 request 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 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.

#### PHS Guideline on Infectious Disease Issues in Xenotransplantation

The statutory authority to collect this information is provided under sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264) and the provisions of the Federal Food, Drug, and Cosmetic Act that apply to drugs (21 U.S.C. 301 et seq.). This PHS guideline is revised based on public comment to a previous document entitled "Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation (August 1996)," which published in the **Federal Register** of September 23, 1996 (61 FR 49919). The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and the general public. The PHS guideline is intended to address public health issues raised by xenotransplantation, through identification of general principles of prevention and control of infectious diseases associated with