

Advanced registration is encouraged. Please provide the following information: Name, title, company name, mailing address, telephone number, facsimile number, and e-mail address to Lisa Beaumier at 770-488-7138, FAX 770-488-4127, or lbeaumier@cdc.gov.

If you need additional information, please contact Lisa Beaumier (contact information provided above).

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: July 16, 2004.

Alvin Hall,

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

[FR Doc. 04-16672 Filed 7-21-04; 8:45 am]

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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 (INEELHES)

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 Department of Energy (DOE) Sites: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES).

Times and Dates: 1:30 p.m.—4:45 p.m., August 10, 2004. 8:30 a.m.—2:45 p.m., August 11, 2004.

Place: The Shilo Inn, 780 Lindsay Boulevard, Idaho Falls, Idaho 83402, telephone 208-523-0088 Ext. 100, fax 208-522-7420.

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 MOUs signed in 1996 and 2000, 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, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, 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 of CDC and the Administrator of ATSDR 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 to serve as a vehicle for communities, American Indian Tribes, and labor to express concerns and provide advice and recommendations to CDC and ATSDR.

Matters To Be Discussed: Agenda items include a presentation of the Sanford Cohen & Associates Report; a report on the Final INEEL Public Health Assessment; the INEEL Worker Cohort Mortality Study; and a Historical Review of the INEEL Dose Reconstruction Project: CDC's Perspective. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Ms. Natasha Friday, Executive Secretary, INEELHES, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, 1600 Clifton Road, NE. (E-39), Atlanta, Georgia 30333, telephone (404) 498-1800, fax (404) 498-1811.

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: July 16, 2004.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0114]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 23, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Institutional Review Boards—(OMB Control Number 0910-0130)—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (IRBs) are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the

basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and

clinical investigators are providing adequate protections to human subjects participating in clinical research.

In the **Federal Register** of March 17, 2004 (69 FR 12700), the agency requested comments on the proposed collection of information. FDA received one comment. The comment strongly disagreed with the estimate of the time required to transcribe and type the minutes of IRB meetings, to maintain records of continuing review activities, and to make copies of all correspondence between the IRB and investigative member records and of written IRB procedures. The comment explained that the burden estimate should include the time required to

keep membership lists current, distribute educational materials to members, orient new members, instruct researchers and their staffs about IRB requirements, provide information to institutions, attend IRB meetings, transcribe discussions, incorporate all revisions into typed minutes and into the official IRB correspondence that is issued to investigators, collate materials, stamp, file, keypunch database entry, and other responsibilities. FDA has considered the comment and has revised the burden estimate to 100 hours.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	5,000	14.6	73,000	100	7,300,000
Total					7,300,000

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

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 5,000 IRBs. The IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 100 hours of person-time per meeting are required to meet requirements of the regulation.

Dated: July 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-16628 Filed 7-21-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0296]

Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

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 the good laboratory practice (GLP) for nonclinical laboratory studies regulations.

DATES: Submit written or electronic comments on the collection of information by September 20, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 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: Denver Presley, Office of Management Programs, (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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 these topics: (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.