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 1996, 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. Community Involvement is a critical part of ATSDR's and CDC's energy-related research and activities and input from members of the ICHHP is part of these efforts. The ICHHP will work with the HHES to provide input on American Indian health effects at the Hanford, Washington site.

PURPOSE: The purpose of this meeting is to address issues that are unique to tribal involvement with the HHES, including a presentation and discussion on the DOE Richland Indian Office, update on tribal cooperative agreements, and agency updates.

MATTERS TO BE DISCUSSED: Agenda items will include a dialogue on issues that are unique to tribal involvement with the HHES. This will include updating tribal members of the cooperative agreement activities in environmental health capacity building and providing support for tribal involvement in and representation on the HHES.

Agenda items are subject to change as priorities dictate.

CONTACT PERSONS FOR MORE INFORMATION: Leslie C. Campbell, Executive Secretary HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE; M/S E–56, Atlanta, Georgia 30333, telephone 1–888/42–ATSDR (28737), fax 404/639–6075.

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: October 19, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–27722 Filed 10–22–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Hanford 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: Hanford Health Effects Subcommittee (HHES).

Times and Dates: 8:30 a.m.–5 p.m., November 18, 1999; 8 a.m.–4 p.m., November 19, 1999.

Place: Cavanaughs at Columbia Center, 1101 North Columbia Center Boulevard, Kennewick, Washington 99336. Telephone: 509/783–0611.

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

Background: Under a Memorandum of Understanding (MOU) 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.

In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 1996, 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, 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 receive an update from the Inter-tribal Council on Hanford Health Projects; to review and approve the Minutes of the previous meeting; to receive updates from ATSDR/NCEH and NIOSH; to receive reports from the Outreach, Public Health Assessment, Public Health Activities, and the Studies Workgroups; and to address other issues and topics, as necessary.

Matters To Be Discussed: Agenda items include a presentation and discussion on the health effects subcommittee evaluations, Health of Hanford November 3 & 4 meeting update, issues related to combining doses from multiple environmental exposures, and a presentation and discussion on current activities with Consortium for Risk Evaluation and Stakeholder participation (CRESP).

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Leslie C. Campbell, Executive Secretary, HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E–56, Atlanta, Georgia 30333, telephone 1–888/42–ATSDR(28737), fax 404/639–6075.

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: October 19, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–27723 Filed 10–22–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4329]

Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 for filing objections and requests for a hearing on a regulation or order.

DATES: Submit written comments on the collection of information by December 27, 1999.

ADDRESSES: 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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 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.

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12 (OMB Control Number 0910–0184—Extension)

Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), within 30 days after publication of a regulation or order, any person adversely affected by such regulations or order may file objections and request a public hearing. The implementing regulations for these statutory requirements are found at 21 CFR 12.22, which sets forth the format and instructions for filing objections and requests for a hearing. Each objection for which a hearing has been requested must be separately numbered and specify with particularity the provision of the regulation or the proposed order objected to. In addition, each objection must include a detailed description and analysis of the factual information to be presented in support of the objection as well as any report or other document relied on, with some exceptions. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis only for the purpose of determining whether a hearing request is justified. The description and analysis do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	60	1	60	20	1,200

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

The burden estimate for this collection of information is based on agency data received on this administrative procedure for the past 3 years. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately 60 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: October 18, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–27698 Filed 10–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2097]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing