

Type of respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
Paying Patrons	25	1	.17
Key Intermediaries	50	1	.25

2. Childhood Lead Poisoning Prevention Program Quarterly Report (0920-0282)—Extension—The National Center for Environmental Health requests an extension of the Childhood Lead Poisoning Prevention Program Quarterly Report. Section 317A of the Public Health Service Act as amended by The Lead Contamination Control Act of 1988 and the Preventive Health Amendments of 1992, mandates that grant applicants report quarterly the number of infants and children screened for elevated blood lead levels, the number found to have elevated blood lead levels, the number and type of medical referrals made for them, and the outcome of such referrals. State and local health agencies are the principal delivery points for childhood lead screening and related medical and environmental management activities. In FY 1998, CDC awarded 41 grants to fund childhood lead poisoning prevention programs. The purpose of the quarterly report is to report data collected by CDC's grantees. The report consists of narrative and data sections. The narrative section (1) provides highlights of quarterly activities, (2) reports issues and activities that have significant impact on the program, and (3) lists objectives and discusses progress towards meeting those objectives. The data section provides (1) screening and case confirmation activities, (2) environmental inspection and hazard remediation activities, and (3) medical case management activities. The total annual burden hours are 328.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
Grantees	41	4	2

Kathy Cahill,

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

Public Health Service Activities and Research at DOE Sites; Citizens Advisory Committee; Notice of Meeting

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Fernald Health Effects Subcommittee; Hanford Health Effects Subcommittee; Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee; and Savannah River Site Health Effects Subcommittee; and the Inter-tribal Council on Hanford Health Projects: Meetings.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the National Center for Environmental Health (NCEH) and the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the following Federal advisory committee meetings.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites.

Times and Dates: 8 a.m.-5 p.m., December 8, 1998; 8:30 a.m.-5:30 p.m., December 9, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801-532-3344, fax 801-531-0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 150 people.

Background: The Department of Health and Human Services (HHS) and the Department of Energy (DOE) have two Memoranda of Understanding (MOU) for public health activities and research at DOE sites. One transferred the responsibility for the management and conduct of energy-related analytic epidemiologic research to HHS, and HHS subsequently delegated program responsibility to CDC. The other is a separate MOU between ATSDR and DOE. This MOU addresses ATSDR public health responsibilities around DOE sites. In addition, ATSDR is required by law (Sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act) to conduct public health assessments, and where appropriate, other health activities, many of which are conducted at DOE sites.

Implementing these MOUs requires significant interaction with communities

living in proximity to DOE sites. This committee was chartered in response to the requests by representatives of the communities surrounding DOE sites to provide consensus advice and recommendations on community concerns related to CDC's and ATSDR's activities related to the sites.

Purpose: This committee provides 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 respective DOE sites. Activities focus on providing a forum for community, American Indian Tribal, and labor interaction, and 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 will include presentations from each of the four established subcommittees; status of the Advisory Committee for Energy-Related Epidemiologic Research Subcommittee for Community Affairs; up to four break-out sessions with presentations post break-out; proposed evaluation of the health effects subcommittees; group discussions and public comments.

Name: Fernald Health Effects Subcommittee (FHES).

Time and Date: 8:30 a.m.–4 p.m., December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801-532-3344, fax 801-531-0705.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the Fernald, Ohio, site.

Matters to be Discussed: Agenda items include an update on worker studies related to the Fernald site from NIOSH; an update on risk assessment from NCEH; selection of FHES representative for an evaluation project; and subcommittee discussion.

Name: Inter-tribal Council on Hanford Health Projects (ICHHP) in Association with the Hanford Health Effects Subcommittee (HHES).

Time and Date: 8 a.m.–12 noon, December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801-532-3344, fax 801-531-0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The purpose of this meeting is to address issues that are unique to tribal involvement with the HHES, including considerations regarding a proposed medical monitoring program and discussion of cooperative agreement activities designed to provide support for capacity-building activities in tribal environmental health expertise and for tribal involvement in HHES.

Matters to be Discussed: Agenda items will include a dialogue on issues that are unique to tribal involvement with the HHES. This will include exploring cooperative agreement activities in environmental health capacity building and providing support for tribal involvement in and representation on the HHES.

Name: Hanford Health Effects Subcommittee (HHES).

Times and Dates: 1 p.m.–5 p.m., December 10, 1998; 8:30 a.m.–3:30 p.m., December 11, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801-532-3344, fax 801-531-0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the Hanford Nuclear Reservation.

Matters to be Discussed: Agenda items will include an update from the ICHHP; the

review and approval of Minutes of the previous meeting; updates from ATSDR, NCEH, and NIOSH; reports from the Outreach, Public Health Assessment, Public Health Activities, and Studies Workgroups; and other issues and topics as necessary.

Name: Idaho National Engineering and Environmental Laboratory Health Effects Subcommittee (INEELHES).

Time and Date: 8:30 a.m.–5:30 p.m., December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801-532-3344, fax 801-531-0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the INEEL.

Matters to be Discussed: Agenda items include an update on the status of research at the INEEL, discussion on document management at DOE; and subcommittee discussions.

Name: Savannah River Site Health Effects Subcommittee (SRSHE).

Time and Date: 8:30 a.m.–5:30 p.m., December 10, 1998.

Place: Salt Lake City Hilton, 150 West 500 South, Salt Lake City, Utah 84101, telephone 801-532-3344, fax 801-531-0705.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: This subcommittee reviews and provides consensus advice to CDC and ATSDR on their public health activities and research at the SRS.

Matters to be Discussed: Agenda items include an update from ATSDR on its research; the schedule for release to the public of the Phase II report; presentations by NCEH, ATSDR, and NIOSH on the design of their respective web pages; and subcommittee discussion.

All agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT:

Information on the HHES and the ICHHP may be obtained from Leslie C. Campbell, Executive Secretary, HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE (E-56), Atlanta, GA 30333, telephone 1-800-447-1544, fax 404-639-6075.

Information on the FHES may be obtained from Steven A. Adams, Executive Secretary, FHES, Radiation Studies Branch (RSB), Division of Environmental Hazards and Health

Effects (DEHHE), NCEH, CDC, 4770 Buford Highway, NE, (F-35), Atlanta, Georgia 30341-3724, telephone 770-488-7040, fax 770-488-7044.

Information on the INEELHES may be obtained from Arthur J. Robinson, Jr., Executive Secretary, INEELHES, RSB, DEHHE, NCEH, CDC, 4770 Buford Highway, NE, (F-35), Atlanta, Georgia 30341-3724, telephone 770-488-7040, fax 770-488-7044. Information on the SRSHEs may be obtained from Paul G. Renard, Executive Secretary, SRSHEs, RSB, DEHHE, NCEH, CDC, 4770 Buford Highway, NE, (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: November 13, 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

Food and Drug Administration

[Docket No. 98N-1000]

Danbury Pharmacal, Inc.; Withdrawal of Approval of 61 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 61 abbreviated new drug applications (ANDA's). Danbury Pharmacal, Inc., notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: December 21, 1998.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug