

Matters To Be Discussed: The panel will gather information regarding the use of vaccinia (smallpox) vaccine.

Contact Person for More Information:

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The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 29, 2002.

John Burckhardt,

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

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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: Savannah River Site Health Effects Subcommittee (SRSHEs)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), and the Agency for Toxic Substances and Disease Registry (ATSDR) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee (SRSHEs).

Time and Date: 8:30 a.m.-4:45 p.m., June 6, 2002.

Place: Radisson Riverfront Hotel Augusta, 2 10th Street, Augusta, Georgia 30901, telephone (706) 722-8900, fax (706) 724-0044, www.radisson.com.

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, CDC, and the Administrator, ATSDR, regarding community 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 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: Update on Department of Labor/Department of Energy Workers Occupational Illness Compensation Program; Overview of Process on Risk Based Screening Criteria and Where it is Going; International Atomic Energy Administration Recommendations; ATSDR Needs Assessment; American College of Preventive Medicine Initiatives Update; and ATSDR/Tritium Health Consult on Potential Tritium Exposures at SRS. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Phillip Green, Executive Secretary, SRSHEs, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, 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: April 29, 2002.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

An FDA/Industry Dialog on the Application Submission Process; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

The Food and Drug Administration (FDA) is announcing two public workshops, both entitled "An FDA/Industry Dialog on the Application Submission Process." The purpose of the public workshops is to discuss common application deficiencies and strategies to avoid these deficiencies leading to faster approval times. Staff from the Center for Biologics Evaluation and Research (CBER) will provide general information on the review process and options to consider. CBER staff also will lead discussion groups designed to respond to your general issues and questions on submission requirements. These discussion groups will be established based on the input provided to CBER on your issues relative to the purpose of this workshop.

Date and Time: Send registration and issues by May 17, 2002, for the May 29, 2002, workshop and by June 14, 2002, for the June 26, 2002, workshop. See table 1 of this document.

Location: See table 1 of this document.

TABLE 1

Meeting address	Dates and local time	FDA contact person
Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814, 301-657-1234.	May 29, 2002, from 9 a.m. to 5 p.m.	Kathy Eberhart.