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: Fernald Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 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: Fernald Health Effects Subcommittee.

Time and Date: 9 a.m.–4 p.m., August 22, 2001.

Place: The Plantation Conference Center, 9660 Dry Fork Road, Harrison, Ohio 45030, telephone, 513/367–5610.

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 a presentation from COSMOS Corporation on the Evaluation of the Health Effects Subcommittee Advisory Process, presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health (NIOSH), and ATSDR on updates regarding progress of current studies.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mike Donnelly, Deputy Chief, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, NE. (E–39), Atlanta, GA 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 10, 2001.

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

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 66 FR 38289–38290, dated July 23, 2001) is amended to retitle and revise the functional statement of the Arctic Investigations Program (AIP), National Center for Infectious Diseases (NCID).

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statement for the Arctic Investigations Program (CFJ) and insert the following:

Arctic Investigations Program (CRJ). (1) Conducts surveillance of infectious diseases and conditions that impact the health of all residents of the circumpolar region with special emphasis on diseases of high incidence and concern among indigenous peoples of these regions; (2) designs and conducts epidemiologic studies to investigate the causes and risk factors for infectious diseases among residents of the Arctic and sub-Arctic, and conducts long-term studies to determine sequelae of various etiologic agents; (3) conducts laboratory research to evaluate existing laboratory tests, modifies methods as needed to apply the technology in the Arctic health-care setting, and develops new methods for diagnosis, treatment, and follow-up of health problems; (4) designs and implements studies to evaluate strategies for control of infectious diseases among residents and travelers in the Arctic in collaboration with, the State of Alaska, foreign ministries of health, universities, National Institutes of Health, organizations in Alaska, and other programs within CDC; (5) provides epidemiologic, statistical, computer, and laboratory consultation to organizations in Alaska, other health providers, and public and private health agencies; (6) assists local, national, and international agencies and organizations in developing guidelines for infectious disease prevention and control applicable to Arctic residents; (7) disseminates information on problems of particular import for residents of circumpolar regions; (8) provides training and technological assistance in epidemiology, statistics, and laboratory methodology to health-care personnel working or planning to conduct research in the Arctic; (9) participates in the Arctic Council proceedings, the International Union for Circumpolar activities and other international collaborative efforts to improve the health of all circumpolar populations; and (10) and the predominate Federal agency conducting infectious diseases research in the Arctic, provides local input as needed to the Office of the Director CDC, the Interagency Arctic Research and Policy Committee, Arctic Research Commission, and National Science Foundation as established under the U.S. Arctic Research and Policy Act of 1984.

Office of the Director (CRJ1). (1) Manages, prioritizes, directs, and coordinates the activities of the Arctic Investigation Program (AIP); (2) provides leadership and guidance on policy, program planning and development, program management, and operations; (3) provides AIP-wide administrative services, and coordinates or assures coordination with the appropriate NCID and CDC staff offices on administrative and program matters; (4) provides liaison with other Governmental agencies, international organizations, and other outside groups; (5) advises and represents the Director,

NCID on policy matters concerning American Indians and Alaska Natives and on Arctic health issues in general; (6) responsible for budget planning, formulation, program budget execution, monitoring, and response to budget audits and reviews; (7) responsible for facility management, security, and employee safety; (8) responsible for the editing, clearance, and tracking of manuscripts for publication, abstracts for presentation, and protocols for Institutional Review Board (IRB) and human subjects review; (9) provides technical aid, consultation, and training to AIP staff on health education, behavioral science, distance education, community organization, and electronic, print, and oral communications; and sponsors and participates in national and international meetings and conferences.

Epidemiology Activity (CRJ2). (1) Conducts epidemic investigations, surveillance, and special studies to investigate the causes, risk factors, and prevention of infection diseases among residents of the Arctic and sub-Arctic; (2) analyzes demographic and disease information and other risk factors that contribute to disease morbidity and mortality; (3) develops, evaluates, and implements prevention and control strategies; (4) provides consultation and technical assistance on surveillance and epidemiologic investigations to other agencies and public and private health-care providers; (5) together with the Laboratory and the Biostatistics and Information Branches develops study protocols and coordinates collaborative research projects involving other agencies, universities, and outside researchers; (6) provides training for Epidemic Intelligence Service Officers, visiting fellows and students; (7) advises AIP staff on health education/communication strategies; and (8) prepares reports and manuscripts for publication.

Laboratory Research Activity (CRJ3). (1) Conducts microbiologic, immunologic, and molecular-based studies directed toward the detection, identification, characterization, tracking, and understanding of the pathogenic mechanisms of infectious agents causing diseases of high incidence among residence of the circumpolar regions; (2) establishes and maintains laboratory surveillance and quality assurance procedures for microbial agents targeted for prevention and control; (3) responsible for the safety and security of the laboratory, and maintenance of the security and integrity of a computerized specimen bank; (4) evaluates existing laboratory assays, or develops new assays for the detection or measurement of antibodies, antigens, nucleic acids, or other markers of microbial agents responsible for infectious diseases and chronic diseases with known or possible infectious etiology; (5) provides laboratory support for epidemiologic studies and outbreak investigations initiated by the Epidemiology Branch and serves as a resource laboratory for the State of Alaska, Section of Laboratories, the Alaska Native Medical Center, and laboratories of other Alaska Native Health Corporations; (6) responsible for maintaining the necessary licensures (NRC, CLIA and Select Agents) required for laboratory studies conducted at AIP; (7) Provides training for visiting fellows, graduate, and undergraduate students pursuing careers in public health laboratory practice; (8) prepares reports, abstracts, and manuscripts for publication; and (9) provides general laboratory consultation to other agencies, public and private health care providers, and researchers conducting studies in Arctic regions.

Biostatistics and Information Management Activity (CRJ4). (1) Develops and maintains computerized database of information gathered as part of AIP's epidemiologic and laboratory studies; (2) provides statistical methodology, participates in the design and analysis, and performs data entry for Program's epidemiologic investigations and surveillance systems; (3) together with the Epidemiology and the Laboratory Branches, designs disease reporting systems for ongoing surveillance; (4) provides statistical consultation for Program staff and other CDC and public health officials; (5) is responsible for the integrity, security, and maintenance of computerized database for a serum bank consisting of 500,000 aliquots of serum from 100,000 Alaskan Natives; (6) is responsible for the operation, maintenance, and upgrading of all computer systems; (7) provides computer training and user support for all program staff; (8) assists in acquisition, translation, and analysis of computerized data from external sources; and (9) prepares reports and manuscripts for publication and provides consultation to other agencies, public and private health-care providers, and researchers.

Dated: July 13, 2001.

Jeffrey P. Koplan,

Director.

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BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 16 and 17, 2001, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Whetstone and Walker Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 16, 2001, the committee will discuss the efficacy and safety of submission tracking number (STN) 103950 Kineret™ (anakinra), Amgen, Inc., for reduction in signs and symptoms of active rheumatoid arthritis. On August 17, 2001, the committee will discuss safety updates for Enbrel™ (etanercept), Immunex, and Remicade™ (infliximab), Centocor, for the treatment of rheumatoid arthritis.

Procedure: On August 16, 2001, from 8 a.m. to 5 p.m. and on August 17, 2001, from 10 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 10, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 10, 2001,