Matters To Be Discussed

Agenda items will include options for relationships between the tribes and ATSDR and CDC regarding the study of health effects from past, current, or future releases of radioactive and hazardous materials into the environment at Hanford, and proposed actions based on the findings of ATSDR and CDC health research and public health activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information

Linda A. Carnes, Health Council Advisor, ATSDR, E–28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 404/639–0730, FAX 404/639–0759.

Dated: June 30, 1995.

Carolyn J. Russell,

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

[FR Doc. 95–16890 Filed 7–10–95; 8:45 am]

BILLING CODE 4163–70–M

Citizens Advisory Committee on Public Health Service 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 Public Health Service Activities and Research at DOE Sites: Hanford Health Effects Subcommittee.

Times and Dates: 8 a.m.–5:30 p.m., July 27, 1995; 7 p.m.–8 p.m., July 27, 1995; 8 a.m.–3:30 p.m., July 28, 1995.

Place: Red Lion Inn, 2525 North 20th, Pasco, Washington 99301, telephone (509) 547–0701, FAX (509) 547–4278.

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

Background

A Memorandum of Understanding (MOU) was 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, 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, 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 delegated program responsibility to CDC.

Purpose

The purpose of this meeting is to receive updates on issues related to the Technical Steering Panel and declassification of DOE documents; discuss issues and develop approaches to Public Outreach activities with ATSDR support; develop approaches to ATSDR and CDC health studies and medical monitoring programs, and receive updates on the Hanford Thyroid Disease Project and Lowell Sever's studies.

Matters to be Discussed

Agenda items include ATSDR's medical monitoring options, ATSDR's planning for a medical assistance program, current ATSDR health assessment activities. The subcommittee will solicit concerns which they will ask ATSDR and CDC to address.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information

Linda A. Carnes, Health Council Advisor, ATSDR, E–28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone (404) 639–0730, FAX (404) 639–0759.

Dated: June 30, 1995.

Carolyn J. Russell,

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

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BILLING CODE 4163–70–M

Food and Drug Administration

[Docket No. 95D–0164]

FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document concerning the use of pilot facilities for the development and manufacture of biological products. The guidance document, entitled ''Center for Biologics Evaluation and Research; Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Guidance,'' provides guidance by the Center for Biologics Evaluation and Research (CBER) to manufacturers of biological products to clarify the licensing requirements for the use of small scale and pilot facilities for the development and manufacture of biological products. These facilities are sometimes collectively referred to by industry as pilot facilities. This guidance document is intended to provide increased flexibility for industry without diminishing public health protection.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of the document. Two copies of all comments are to be submitted, except that individuals may submit one copy. The comments received are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 400 South, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: CBER recognizes that development of important new biological products is expensive and time consuming, and that companies must be able to forecast and evaluate their expenditures for this process. Constructing a new facility to manufacture a product that has not been fully tested in clinical trials could result in a company being unable to recover a major capital expenditure if the product is not ultimately brought to market. CBER also recognizes that for some companies the best financial option may be the use of a pilot facility where a product may be manufactured at a smaller scale than would be ultimately desired for an approved product.

While CBER does not object to the use of pilot production facilities for the manufacture of clinical material, many companies are concerned that these facilities would not be eligible for establishment licensure. This guidance document is intended to clearly articulate that pilot facilities are eligible for licensure. The guiding principle is that an application for establishment licensure can be made for any facility