1. Princeton/LeClaire Agency, Inc., Princeton, Iowa; to engage *de novo* in leasing activities, pursuant to § 225.25(b)(5)(i) of the Board's Regulation Y.

B. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. First Hawaiian, Inc., Honolulu, Hawaii; to engage *de novo* through its subsidiaries, Pioneer Federal Savings Bank, and First Hawaiian Creditcorp, Inc., both of Honolulu, Hawaii, in community development activities, pursuant to § 225.25(b)(6) of the Board's Regulation Y. The geographic scope for these acitivities is limited to the state of Hawaii.

Board of Governors of the Federal Reserve System, July 5, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–16900 Filed 7–10–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity has made final findings of scientific misconduct in the following case:

James Urban, M.D., Ph.D., California Institute of Technology: The Office of Research Integrity (ORI) has found that James L. Urban, M.D., Ph.D., engaged in scientific misconduct. This finding is based on an investigation by the California Institute of Technology (CIT) which concluded that Dr. Urban committed serious errors in judgment and serious scientific misconduct in connection with fabricating certain research data in two scientific papers that were published in the journal *Cell.* The first paper is J. Urban, V. Kumar, D. Kono, C. Gomez, S. Horvath, J. Clayton, D. Ando, E. Sercarz, and L. Hood, ''Restricted Use of T Cell Receptor V Genes on Murine Autoimmune Encephalomyelitis Raises Possibilities for Antibody Therapy,'' *Cell.* 54: 577–592 (1988). The second paper at issue is J.L. Urban, S.J. Horvath and L. Hood, ''Autoimmune T Cells: Immune Recognition of Normal and Variant Peptide Epitopes and Peptide-based Therapy,'' *Cell.* 59: 257–271 (1989). Specifically, the CIT Report states that Dr. Urban admitted that he fabricated two control lanes reported in Figure 5 of the *Cell.* 54 paper. With respect to the *Cell.* 59 paper, the CIT Report states that Dr. Urban admitted that he circulated draft copies of the manuscript that contained fabricated data in order to circumvent both the internal and external review processes.

Dr. Urban has accepted the ORI findings and agreed to exclude himself voluntarily, for a period of three years beginning June 2, 1995, from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4 (Debarment Regulations). This voluntary exclusion does not apply to Dr. Urban's current or future practice of clinical medicine or training, whether as a resident, fellow, or licensed practitioner, unless that practice involves the proposing, conducting, or reporting of biomedical or behavioral research or research training. Dr. Urban also agreed to exclude himself voluntarily from serving on any Public Health Service Advisory Committees, Boards, and/or peer review committees for the same three-year period.

ORI acknowledges that Dr. Urban cooperated with the CIT Investigation Committee during its investigation of allegations of scientific misconduct and with ORI in its resolution of this matter.

FOR FURTHER INFORMATION CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 301–443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 95–16961 Filed 7–10–95; 8:45 am]

BILLING CODE 4160–17–P

Agency for Toxic Substances and Disease Registry

Public Meeting of the Inter Tribal Council, in Association With the Meeting of the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Hanford Health Effects Subcommittee

The Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Public Meeting of the Inter Tribal Council (ITC), in association with the meeting of the Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Hanford Health Effects Subcommittee.

Time and Dates: 9 a.m.–4:30 p.m., July 26, 1995.

Location: The 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.

Community involvement is a critical part of ATSDR's and CDC's energy-related research and activities and input from members of the ITC is part of these efforts. The ITC will work with the Hanford Health Effects Subcommittee (HHES) to provide input on Native American health effects at the Hanford, Washington, site.

Purpose

The purpose of this meeting of the ITC is to discuss issues that are unique to tribal involvement with HHES including considerations regarding a proposed medical monitoring program and explorations of options and alternatives to providing support for tribal involvement in HHES.

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).

[FR Doc. 95–16889 Filed 7–10–95; 8:45 am]

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