Place: The Plantation, 9660 Dry Fork Road, Harrison, Ohio 45020, 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 an MOU signed in 1996, 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, an 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, 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, American Indian Tribes, and labor 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, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters To Be Discussed: Agenda items include: presentations from the National Center for Environmental Health (NCEH) regarding current activities, the National Institute for Occupational Safety and Health and ATSDR will provide updates on the progress of current studies, and an overview of the Fernald Health Effects Subcommittee's mission and activities will be part of the evening session.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Steven A. Adams, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE. (M/S F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: October 15, 1997.

Nancy C. Hirsch,

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

[FR Doc. 97–27792 Filed 10–20–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control: Meeting

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) announces the following committee meeting.

Name: Advisory Committee for Injury Prevention and Control (ACIPC).

Time and Date: 1–4:30 p.m., November 18, 1997.

Place: Sheraton Washington Hotel, 2660 Woodley Road at Connecticut Avenue, NW, Washington, DC 20008.

Status: Open to the public, limited only by the space available.

Purpose: The Committee advises and makes recommendations to the Secretary, the Assistant Secretary for Health, and the Director, CDC, regarding feasible goals for the prevention and control of injury. The Committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The Committee provides advice on the appropriate balance and mix of intramural and extramural research, including laboratory research, and provides guidance on intramural and extramural scientific program matters, both present and future, particularly from a long-range viewpoint. The Committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Committee recommends areas of research to be supported by contracts and provides concept review of program proposals and announcements.

Matters To Be Discussed: The Science and Program Review Work Group (SPRWG) will meet to discuss a research grants update, upcoming program announcements, and related issues. Following the Work Group meeting, the full Committee will meet to discuss (1) Safe America Partnership Council; (2) National Partnership Council including Federal and corporate components; (3) a report from SPRWG; and (4) status of the Institute of Medicine study on injury prevention and control.

Agenda items are subject to change as priorities dictate.

Contact Person for more Information: Mr. Thomas E. Blakeney, Executive Secretary, ACIPC, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, Georgia 30341–3724, telephone 770/488–1481.

Dated: October 15, 1997.

Nancy C. Hirsch,

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

[FR Doc. 97–27786 Filed 10–20–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs 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). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on November 13 and 14, 1997, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 13, 1997, the committee will discuss new drug application (NDA) 20–788, Propecia™ (finasteride 1 milligram tablets, Merck Research Laboratories), for treatment of androgenetic alopecia to increase hair growth and to prevent further hair loss. On November 14, 1997, the committee will participate in a scientific discussion of clinical trial design questions for products intended for the treatment of burn wounds. This is one segment of an overall effort by the agency to develop a guidance document on wound healing products.

Procedure: 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 November 4, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m., and between approximately 1 p.m. and 1:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 4, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27816 Filed 10–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices 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). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on November 17, 1997, 8:30 a.m. to 4:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: John C. Monahan, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss general issues and vote on an original premarket approval application (PMA) for an ultrasound bone sonometer and an original PMA for a breast impedance scanner.

Procedure: 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 November 10, 1997. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 10, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 10, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27817 Filed 10–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0349]

Guidance for Industry on SUPAC–IR: Immediate Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Level 1 guidance for industry entitled ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Manufacturing Equipment Addendum.'' This guidance is intended to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and abbreviated antibiotic applications (AADA's) who wish to change equipment during the postapproval period. This guidance document represents the agency's current thinking on scale-up and postapproval equipment changes (SUPAC) for immediate release dosage forms regulated by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–623), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms—Manufacturing Equipment Addendum.'' This guidance is intended to provide recommendations to pharmaceutical manufacturers using CDER'S Guidance for Industry on ''Immediate Release Solid Oral Dosage Forms, Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (SUPAC–IR), which was issued in November 1995. The manufacturing equipment addendum may be used in conjunction with the SUPAC–IR guidance in determining what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations in sections V and VI.A of the SUPAC–IR guidance.