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]

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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.