Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shiew-Mei Huang, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5671.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.''

The pharmacokinetics (PK) and pharmacodynamics (PD) of drugs primarily eliminated through the kidneys may be altered by impaired renal function to the extent that the dosage regimen needs to be changed from that used in patients with normal renal function. Although the most obvious type of change arising from renal impairment is a decrease in renal excretion (or possibly renal metabolism) of a drug or its metabolites, renal impairment also has been associated with other changes, such as changes in hepatic metabolism, plasma protein binding, and drug distribution. These changes may be particularly prominent in patients with severely impaired renal function and have been observed even when the renal route is not the primary route of elimination of a drug. Thus, for most drugs that are likely to be administered to patients with renal impairment, PK/PD characterization may need to be assessed in subjects with such impairment to provide appropriate dosing recommendations.

The draft guidance provides specific information on when studies of PK in patients with impaired renal function should be performed and when they may be unnecessary. It also addresses the design and conduct of PK/PD studies in patients with impaired renal function, the design and conduct of PK/PD studies in end stage renal disease (ESRD) patients treated with hemodialysis, the analysis and reporting of the results of such studies, and representation of these results in approved product labeling.

This draft guidance represents the agency's current thinking on conducting PK/PD studies on patients with impaired renal function. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guidance is available on the Internet using the World Wide Web (www) at http://www.fda.gov/cder/guidance.htm.

Dated: June 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–15635 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of public advisory committees of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Joint meeting of the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on July 16, 1997, 8:30 a.m. to 5 p.m.

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

Contact Person: Andrea G. Neal or Tracy Riley, 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), codes 12541 and 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss data submitted regarding the over-the-counter status of new drug application (NDA) 20-834, Rogaine® (minoxidil 5% topical solution), The Pharmacia & Upjohn Co. for use as a hair growth stimulant by men with androgenetic alopecia.

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 July 3, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 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: June 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15632 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Circulatory System 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 July 28, 1997, 9:30 a.m. to 6 p.m., and July 29, 1997, 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn—Gaithersburg, Walker/Whetstone Salons, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee

Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 28, 1997, the committee will discuss a premarket approval application (PMA) for a transmyocardial revascularization device. On July 29, 1997, the committee will discuss a PMA for a laser sheath for pacing lead extraction.

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 July 18, 1997. Oral presentations from the public will be scheduled between approximately 9:30 a.m. to 10:30 a.m. on July 28, 1997, and between approximately 8:30 a.m. to 9:30 a.m. on July 29, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 18, 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: June 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15633 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Biological Response Modifiers 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 July 24 and 25, 1997, 8 a.m. to 5:30 p.m.

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

Contact Person: William Freas, Gail M. Dapolito, or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 24, 1997, during the morning session, the committee will discuss Neumega® (oprelvekin, recombinant human interleukin eleven, rhIL–11), Genetics Institute. An indication is sought for Neumega® for the prevention of chemotherapy-induced thrombocytopenia and reduction in the need for platelet transfusions in patients with nonmyeloid malignancies. During the afternoon session, the committee will discuss a premarket approval application for a device to concentrate CD34 positive cells in autologous peripheral blood stem cell products used for hematopoietic rescue. General data requirements for cell selection devices for hematopoietic rescue will also be discussed. On July 25, 1997, the committee will discuss Rituximab (C2B8 monoclonal antibody), IDEC. The company is seeking an indication for Rituximab as a treatment for patients with relapsed or refractory low grade or follicular B-cell non-Hodgkin's Lymphoma. The committee will also discuss Neupogen®, (Filgrastim, granulocyte colony-stimulating factor), Amgen. An indication is sought for use of Neupogen® to reduce the duration of neutropenia, fever, hospitalization, and antibiotic use in patients with acute myeloid leukemia.

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 July 17, 1997. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 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 July 17, 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: June 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15634 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of public advisory committees of the Food and Drug Administration (FDA). This meeting will be open to the public.

Name of Committees: Joint meeting of the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee with Representation from the Peripheral and Central Nervous System Drugs Advisory Committee.

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

Date and Time: The meeting will be held on July 15, 1997, 8:30 a.m. to 5 p.m.

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

Contact Person: Andrea G. Neal or Kathleen R. Reedy, 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), codes 12541 and 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss data submitted regarding New Drug Application (NDA) 20–802, Excedrin Extra Strength (acetaminophen, aspirin, caffeine) Tablets, Caplets, and Geltabs, 250 milligrams (mg), 250 mg, and 65 mg, respectively, Bristol Myers Squibb, for the pain of migraine.

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 July 3, 1997. Oral