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

presentations from the public will be scheduled between approximately 8:30 a.m. and 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 on 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 6, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15637 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: 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 July 14 and 15, 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 K. 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 July 14, 1997, the committee will discuss biologic licensing application (BLA) 96–1408, Regranex® (becaplermin [PDGF–BB], Chiron Corp., in a carboxymethyl cellulose gel), OMJ Pharmaceuticals, Inc., for treatment of chronic diabetic foot ulcers. On July 15, 1997, the committee will participate in a general scientific discussion regarding the development of a possible future guidance document for chronic cutaneous ulcers. This is one segment of an overall effort by the agency to provide guidance on wound healing products, including a future discussion of products for treatment of burns. The agency encourages investigators, academicians, members of the pharmaceutical industry, consumer groups, and others with information relevant to the topics to respond to the contact person.

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. and 9 a.m., on July 14, 1997; between approximately 8:30 a.m. and 9 a.m., and between approximately 1 p.m. and 1:30 p.m., on July 15, 1997. Time allotted for each presentation may be limited. Those desiring to make formal 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. 97–15638 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: Psychopharmacologic 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 July 14, 1997, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Rhonda W. Stover or Robinette Taylor, 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 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider proposals to reduce the frequency of required white blood cell count monitoring for Clozaril® (clozapine), new drug application (NDA) 19–758, Sandoz Pharmaceutical Corp.

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 7, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 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 7, 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. 97–15761 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F