Dated: June 7, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–15082 Filed 6–20–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Biological Response Modifiers Advisory Committee

Date, time, and place. July 13 and 14, 1995, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, July 13, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; open public hearing, 6 p.m. to 6:30 p.m., unless public participation does not last that long; open public hearing, July 14, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 10:10 a.m.; closed committee deliberations, 10:10 a.m. to 10:30 a.m.; open committee discussion, 10:30 a.m. to 4:30 p.m.; William Freas or Pearline Muckelvene, 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 Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Biological Response Modifiers Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 5, 1995, 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 required to make their comments.

Open committee discussion. On July 13, 1995, the committee will discuss public health concerns in xenotransplantation. On the morning of July 14, 1995, the committee will discuss data in support of the safety of a proposed baboon bone marrow transplant in the treatment of advanced human immunodeficiency virus, type 1, (HIV–1) disease, and a discussion of the safety of clinical transplantation of nonhuman primate tissue into human recipients. In the afternoon, the committee will discuss extracorporeal liver assist devices for treatment of liver failure, followed by a discussion of the utility of polymerase chain reaction in the clinical trials of biologic therapies for hepatitis C.

Closed committee deliberations. On July 14, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications (IND's). This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. July 13 and 14, 1995, 8 a.m., Holiday—Inn Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, July 13, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 5 p.m.; closed presentation of data, July 14, 1995, 8 a.m. to 10 a.m.; open public hearing, 10 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, FAX 301–443–0699, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, 12536.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 7, 1995, 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 required to make their comments.

Open committee discussion. On July 13, 1995, the committee will hear presentations and discuss data submitted regarding the safety and efficacy of alendronate, new drug application (NDA) 20–560 (Fosamax®, Merck), for an osteoporosis indication. On July 14, 1995, the committee will discuss guidance criteria for the development of safe and effective medications for the treatment of obesity.

Closed presentation of data. On July 14, 1995, the committee will hear trade secret and/or confidential commercial information relevant to pending IND's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Joint Meeting of Nonprescription Drugs Advisory Committee With Gastrointestinal Drugs Advisory Committee and With Arthritis Advisory Committee

Date, time, and place. July 13 and 14, 1995, 8:30 a.m., conference rooms D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, July 13, 1995, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open committee discussion, July 14, 1995, 8:30 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; closed committee deliberations, 12 m. to 1 p.m.; open committee discussion, 1 p.m. to 4 p.m.; Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541.

General functions of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Gastrointestinal Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 7, 1995, 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 required to make their comments.

Open committee discussion. On July 13, 1995, the Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee will discuss data relevant to NDA 20–520 to switch Zantac® 75 (ranitidine hydrochloride tablets) (Glaxo, Inc.) from prescription to over-the-counter status for the treatment of heartburn. On July 14, 1995, the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee will discuss data relevant to NDA 20–499 (Bayer Corp.,) and NDA 20–429 (Whitehall-Robins Healthcare). Both NDA's are to switch ketoprofen (12.5 milligrams tablet/caplet) from prescription to over-the-counter status for the temporary relief of minor aches and pains associated with the common cold, toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps, and for reduction of fever.

Closed committee deliberations. On July 14, 1995, the committees will discuss trade secret and/or confidential commercial information relevant to pending IND's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 17, 1995, 4:30 p.m., and July 18, 1995, 8 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA Panel meeting block. Reservations may be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed committee deliberations, July 17, 1995, 4:30 p.m. to 5:30 p.m.; open public hearing, July 18, 1995, 8 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), General Hospital and Personal Use Devices Panel, code 12520.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 10, 1995, 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 required to make their comments.

Open committee discussion. On July 18, 1995, the committee will discuss the classification of general purpose disinfectants and sterilants, and as time permits, will discuss the classification of Apgar timers, infusion stands, and lice detectors and removers.

Closed committee deliberations. On July 17, 1995, FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 19, 1995, 8 a.m., Holiday Inn— Gaithersburg, Whetstone Room, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, 8 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5 p.m.; Daniel Schultz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1307, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in Washington, DC area), General and Plastic Surgery Devices Panel, code 12519.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 1, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss the following issues: (1) Implementation strategy for the draft guidance on medical lasers; and (2) categorization and regulatory considerations for wound dressing devices.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding issues related to new technologies currently under review. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Anti-Infective Drugs Advisory Committee

Date, time, and place. July 20, 1995, 8 a.m., and July 21, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open committee discussion, July 20, 1995, 8 a.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; closed committee deliberations, July 21, 1995, 8:30 a.m. to 4:30 p.m.; Ermona B. McGoodwin or Mary Elizabeth Donahue, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anti-Infective Drugs Advisory Committee, code 12530.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 13, 1995, 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 required to make their comments.

Open committee discussion. During the morning of July 20, 1995, the committee will discuss treatment goals of the short-term therapy of cystitis, including safety and efficacy data for the fosfomycin tromethamine NDA 50–717, Forest Laboratories, Inc./Zambon Corp. During the afternoon, the committee will revisit the FDA/Infectious Diseases Society of America guidelines for evaluating new treatment regimens for urinary tract infections.

Closed committee deliberations. On July 21, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending IND's and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 21, 1995, 8 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations can not be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 12 m.; closed committee deliberations, 12 m. to 1 p.m.; open committee discussion, 1 p.m. to 6 p.m.; Marilyn N. Flack, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ear, Nose, and Throat Devices Panel, code 12522.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before July 10, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss a premarket approval application that seeks to substantiate the safety and effectiveness of a cochlear implant device for use in adults with postlinguistically, profound, sensorineural hearing loss, who obtain little benefit from conventional amplification.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes

in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: June 15, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–15147 Filed 6–20–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Meeting of the NIH Director's Advisory Panel on Clinical Research

Notice is hereby given that the NIH Director's Advisory Panel on Clinical Research, a group reporting to the Advisory Committee to the Director (ACD), National Institutes of Health (NIH), will meet in public session at the William H. Natcher Building (Building 45) Conference Center, Conference Room E1/E2, National Institutes of Health, Bethesda, Maryland 20892, on July 7, 1995, from 8:30 a.m. until approximately 3:30 p.m.

The goal of the Panel is to review the status of clinical research in the United States and to make recommendations to the ACD about how to ensure its effective continuance. Topics to be considered at this and subsequent meetings will include, but not be limited to, financing of clinical research; roles of the General Clinical Research Centers and the NIH Clinical Center; attracting and training future clinical researchers; conduct of clinical trials; and peer review of clinical research.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other special accommodations, should contact the person named below in advance of the meeting.

Attendance may be limited to seat availability. If you plan to attend the meeting as an observer or if you would like additional information, please contact Mrs. Janet Smith, National Institutes of Health, Building 10, Room 1C–116, 10 Center Drive, MSC 1154, Bethesda, Maryland 20892–1154, telephone (301) 402–3444, fax (301) 402–3443, by June 30, 1995.

Effective Date: June 15, 1995.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 95–15155 Filed 6–20–95; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Gene Nutrient Interaction in the Pathogenesis of Congenital Heart Defects.

Date: July 10–11, 1995.

Time: 7 p.m.

Place: Holiday Inn, Bethesda, Maryland.

Contact Person: Anthony M. Coelho, Jr., M.D., Two Rockledge Building, 6701 Rockledge Drive, Room 7182, Bethesda, Maryland 20892–7924, (301) 435–0277.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: SCOR on Ischemic Heart Disease in Blacks.

Date: July 19–20, 1995.

Time: 7 p.m.

Place: Holiday Inn, Chevy Chase, Maryland.

Contact Person: S. Charles Selden, Ph.D., Two Rockledge Building, 6701 Rockledge Drive, Room 7196, Bethesda, Maryland 20892–7924, (301) 435–0288.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in