

5, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

#### Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 20, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 7, 1995.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 95-4057 Filed 2-16-95; 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:

#### Radiological Devices Panel of the Medical Devices Advisory Committee

*Date, time, and place.* March 6, 1995, 8 a.m., Corporate Bldg., conference room 20G, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-590-0044 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 9 a.m., unless public participation does not last that long; open committee discussion, 9

a.m. to 4 p.m.; Robert A. Phillips, 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 Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Radiological Devices Panel, code 12526. If anyone who is planning to attend the meeting will need any special assistance as defined under the Americans with Disabilities Act, please communicate with the contact person.

*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 March 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 clinical data requirements (experimental designs, protocols, quality assurance, etc.) for digital mammography submissions. Copies of a draft protocol are available from the contact person.

#### Blood Products Advisory Committee

*Date, time, and place.* March 23 and 24, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

*Type of meeting and contact person.* Open committee discussion, March 23, 1995, 8 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 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; open committee discussion, 12 m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5:30 p.m.; open committee discussion, March 24, 1995, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 5:30 p.m.; Linda A. Smallwood, Center for Biologics

Evaluation and Research (HFD-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-6700, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Blood Products Advisory Committee, code 12388.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment 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 March 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.* On the morning of March 23, 1995, the committee will discuss and provide recommendations for warnings in the labeling for blood products regarding potential transmission of viral agents. Additionally, the committee will discuss and provide recommendations for the format of blood container labeling. In the afternoon, the committee will discuss the practice of alanine aminotransferase (ALT) testing of blood and plasma donors, and they will provide recommendations. On the morning of March 24, 1995, the committee will discuss pool size for the manufacture of plasma products and, in the afternoon, the committee will participate in a workshop entitled, "Human Tissue Intended for Transplantation and Human Reproductive Tissue: Donor Screening and Infectious Disease Testing." The issues to be discussed at the workshop are: (1) Recommendations for donor screening and infectious disease testing needed to clarify the interim rule for human tissue intended for transplantation (21 CFR 1270) that published in the **Federal Register** of December 13, 1993 (58 FR 65514), (2) draft recommendations for screening and testing donors of human reproductive tissue, and (3) the draft registration form. The agency is announcing the availability, before the meeting, of a draft document on the issues to be discussed at the workshop. Requests for single copies of the draft document may be made to the Division

of Congressional, International, and Consumer Affairs, Center for Biologics Evaluation and Research (HFM-11), 1401 Rockville Pike, rm. 200N, Rockville, MD 20857, 301-594-1800.

**Joint Meeting of the Nonprescription Drugs and the Dermatologic and Ophthalmic Drugs Advisory Committees, Followed by a Session with Pulmonary-Allergy Drugs Committee Representation, and a Joint Meeting with the Arthritis Advisory Committee**

*Date, time, and place.* March 27 and 28, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing a separate meeting of the Arthritis Advisory Committee to be held on March 27, 1995.

*Type of meeting and contact person.* Open committee discussion, March 27, 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 3 p.m., open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5:30 p.m.; open committee discussion, March 28, 1995, 8 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; open committee discussion, 12 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, 301-443-5455, 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 function of the committees.* The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (OTC) (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Dermatologic and Ophthalmic Drugs Advisory Committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders. The Pulmonary-Allergy Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of

pulmonary disease and diseases with allergic and/or immunologic mechanisms. 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 March 22, 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 March 27, 1995, the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee will discuss data relevant to new drug application (NDA) 18-751 to switch econazole nitrate cream 1% (Spectazole®, Johnson & Johnson Consumer Products, Inc.) from prescription to OTC status for the treatment of tinea pedis (athlete's foot). During the afternoon of March 27, 1995, the Nonprescription Drugs Advisory Committee and representatives of the Pulmonary-Allergy Drugs Advisory Committee will discuss data relevant to the efficacy and use of antihistamines for the treatment of the common cold. In the morning on March 28, 1995, the Nonprescription Drugs Advisory Committee and the Arthritis Drugs Advisory Committee will discuss data relevant to NDA 20-512 for ibuprofen suspension (Motrin®, McNeil Consumer Products) for the treatment of fever and of pain in children between 2 and 12 years of age. During the afternoon, the committees will discuss recommendations regarding appropriate OTC indication(s) for muscle relaxants, OTC dose(s) and duration of use, safety profiles, abuse potential, and pharmacokinetic information.

**Subcommittee Meeting of the Antiviral Drugs Advisory Committee on Immunosuppressive Drugs**

*Date, time, and place.* March 30 and 31, 1995, 8 a.m., Holiday Inn, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

*Type of meeting and contact person.* Open committee discussion, March 30, 1995, 8 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; open committee discussion, 12 m. to 6 p.m.; open committee discussion, March 31, 1995, 8 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; open committee discussion, 12 m. to 2 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, 301-443-5455, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531.

*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 acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

*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 a contact person before March 22, 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 March 30, 1995, the subcommittee will discuss data relevant to NDA 20-513 (250 milligrams (mg) capsules) and NDA 20-514 (500 mg tablets), for mycophenolate mofetil (CellCept®, Syntex Laboratories, Inc.), for use in the prophylaxis of organ rejection and treatment of refractory organ rejection in patients receiving allergenic renal transplants. On March 31, 1995, the subcommittee will discuss data relevant to NDA 50-715 (soft gelatin capsules) and NDA 50-716 (oral solution) for cyclosporine microemulsion (Neoral®, Sandoz Pharmaceuticals Corp.) for prophylaxis of organ rejection in kidney, liver, and heart allergenic transplants.

**Immunology Devices Panel of the Medical Devices Advisory Committee**

*Date, time, and place.* March 31, 1995, 9 a.m., Corporate Bldg., 9200 Corporate Blvd., main conference room, Rockville, MD.

*Type of meeting and contact person.* Open public hearing, 9 a.m. to 10 a.m.,

unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Peter E. Maxim, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Immunology Devices Panel, code 12516.

*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 March 15, 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 for a software computer program to assist physicians and laboratory professionals in the database management, calculations, and reporting of results from quantitative measurements of alpha-fetoprotein as an aid in the detection of fetal open neural tube defects.

FDA public advisory committee meetings 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. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open 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.

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: February 14, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*

[FR Doc. 95-4194 Filed 2-16-95; 8:45 am]

BILLING CODE 4160-01-F

#### **Advisory Committees; Notice of Meetings**

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**ACTION:** Notice.

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**MEETINGS:** The following advisory committee meetings are announced:

#### **Allergenic Products Advisory Committee**

*Date, time, and place.* March 10, 1995, 9 a.m., Woodmont Office Complex I, conference room 400-N, 1401 Rockville Pike, Rockville, MD.

*Type of meeting and contact person.* This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open committee discussion on review of research, 9 a.m. to 10 a.m.; closed committee deliberations, 10 a.m. to 11:05 a.m.; open public hearing, 11:05 a.m. to 12:05 p.m., unless public participation does not last that long; Jack Gertzog or Sandy Salins, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike,

Bethesda, MD 20852, 301-827-0314, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Allergenic Products Advisory Committee, code 12388.

*General function of the committee.*

The committee reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

*Agenda—Open public hearing.*

Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee, should communicate with the contact person.

*Open committee discussion.* The committee will discuss the intramural scientific program of the Laboratory of Immunobiochemistry and the clinical research programs of individuals in the Division of Allergenic Products and Parasitology.

*Closed committee deliberations.* The committee will discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

#### **Arthritis Advisory Committee**

*Date, time, and place.* March 27, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing a joint meeting on March 28, 1995, with the Nonprescription Drugs Advisory Committee.

*Type of meeting and contact person.*

Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 5:30 p.m.; Isaac F. Roubein, 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), Arthritis Advisory Committee, code 12532.

*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 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 March 16, 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 new drug application (NDA) 18-922, Lodine® (etodolac) Wyeth-Ayerst Laboratories, which is proposed for the treatment of rheumatoid arthritis.

*Closed committee deliberations.* The committee will review trade secret and/or confidential commercial information relevant to pending investigational new drugs. 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