

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.