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NOTICES

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Food and Drug Administration

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 wilį 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.

MEETING: The following advisory committee meetings are announced:

Joint Meet ng of the Antiviral Drugs Advisory Committee and Nonprescription Drugs Advisory Committee

Date, time, and place. January 11, 1995, 9 a.m. and January 12, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Closed committee deliberations, January 11, 1995, 9 a.m. to 5 p.m.; open committee discussion, January 12, 1995, 8 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that

long; open committee discussion, 12 m. to 5 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), Antiviral Drugs Advisory Committee, code 12531.

General function of the committees. The Antiviral Drugs Advisory 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. 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.

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 January 6, 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 committees will jointly discuss data submitted in support of supplementary new drug application (NDA) 18-828/S-015, to switch acyclovir 200 milligrams (Zovirax(R), Burroughs Wellcome Co.) from prescription to over-the-counter status for the treatment of recurrent genital herpes. Issues and concerns relating to over-the-counter availability of acyclovir for the treatment of recurrent genital herpes were discussed publicly on May 19, 1994; public comment is available for inspection in Docket No. 94N-0006 in FDA's Dockets Management Branch (HFA-305), rm. 1-23, 12420 Parklawn Dr., Rockville, MD.

Closed committee deliberations. On January 11, 1995, the Antiviral Drugs Advisory Committee will discuss trade secret and/or confidential commercial information relevant to pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Anesthetic and Life Support Drugs Advisory Committee

Date, time, and place. January 17 and 18, 1995, 8:30 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, January 17, 1995, 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 11 a.m.; closed committee deliberations, 11 a.m. to 12 m.; open committee discussion, 1 p.m. to 5 p.m.; open committee discussion, January 18, 1995, 8:30 a.m. to 12 m.; closed committee deliberations, 12 m. to 3 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), Anesthetic and Life Support Drugs Advisory Committee, code 12529.

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 the field of anesthesiology and surgery.

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 January 9, 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 NDA 20-478, Sevoflurane(R), Abbott Laboratories, to be indicated as an inhalational anesthetic agent.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to a pending investigational new drug application and NDA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. January 20, 1995, 8:30 a.m., Holiday Inn-Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn-Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 1-800-465-4329, or 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, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5 p.m.; Mary J. Cornelius, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Gastroenterology and Urology Devices Panel, code 12523.

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 January 6, 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 general issues related to a premarket approval application for a metallic mesh stent intended for the relief of urinary obstruction secondary to urethral stricture disease.

Closed committee deliberations. The committee may discuss trade secret and/or confidential commercial information regarding medical devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. January 26 and 27, 1995; 8 a.m. Holiday Inn-Bethesda, Versailles Ballrooms I through III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Closed committee deliberations, January 26, 1995, 8 a.m. to 10:45 a.m.; open public hearing, 10:45 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 6:30 p.m.; open public hearing, January 27, 1995, 8 a.m. to 8:45 a.m., unless public participation does not last that long; open committee discussion, 8:45 a.m. to 6:15 p.m.; Nancy T. Cherry or Stephanie A. Milwit, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-594-1054, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines 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 January 19, 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 January 26, 1995, the committee will consider available clinical data from completed trials and future clinical development of a therapeutic AIDS vaccine. On January 27, 1995, the committee will discuss the influenza virus vaccine formulation for 1995 through 1996. The committee will also hear an update on a vaccine for the prevention of varicella.

Closed committee deliberations. On January 26, 1995, the committee will review trade secret and/or confidential commercial information relevant to pending product licensing applications. 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: December 16, 1994.

Linda A. Suydam,
Interim Deputy Commissioner for Operations.

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