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 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:

Anti-Infective Drugs Advisory Committee

Date, time, and place. March 5, 1997, 8:30 a.m., Bethesda Ramada, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD, and March 6 and 7, 1997, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and III, 8210 Wisconsin Ave., Bethesda, MD. The hotels are in close proximity and have parking available. In addition, there is a public parking garage nearby at 8216 Woodmont Ave.

Type of meeting and contact person. Open public hearing, March 5, 1997, 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 5 p.m.; open committee discussion, March 6, 1997, 8:30 a.m. to 5 p.m.; open committee discussion, March 7, 1997, 8:30 a.m. to 2 p.m.; Ermona B. McGoodwin or Danyiel D'Antonio, 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 Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Anti-Infective Drugs Advisory Committee, code 12530. Please call the hotline for information concerning any possible changes.

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 February 28, 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 required to make their comments.

Open committee discussion. On the morning of March 5, 1997, the committee will discuss supplemental new drug application (NDA) 50–679/S002 Maxipime® for Injection (cefepime hydrochloride, Bristol-Myers Squibb), in the treatment of febrile episodes in neutropenic patients. In the afternoon of March 5, 1997, and on March 6 and 7, 1997, the committee will discuss the draft guidance document entitled ''Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products,'' which is currently in the *Draft-Not for Implementation* stage. Copies of this draft guidance document can be obtained 2 weeks before the meeting from the Drug Information Branch, Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573, FAX: 301–827–4577. An electronic version of this draft guidance document will be available 2 weeks before the meeting via the World Wide Web. To access the draft guidance document on the Internet, connect to CDER's home page at http://www.fda.gov/cder/guidance.htm.

FDA regrets that it was unable to publish this notice 15 days prior to the March 5, 6, and 7, 1997, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Science Board to the Food and Drug Administration

Date, time, and place. March 13, 1997, 9 a.m. to 3 p.m., Sheraton National Hotel, North Ballroom, 900 South Orme St. (Columbia Pike and Washington Blvd.), Arlington, VA.

Type of meeting and contact person. Open committee discussion, 9 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 3 p.m.; Susan A. Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603. Please call the hotline for information concerning any possible changes.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations should notify the contact person before March 3, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be accommodated. All written statements submitted in a timely fashion will be provided to the board.

Open board discussion. The Science Board Subcommittee on Toxicology, which has been established to address

issues related to toxicological testing methods, will provide an update on its activities. The Science Board Subcommittee on FDA Research will present a report to the board on a strategy for optimizing the quality and mission relevance of agency research programs.

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. March 14, 1997, 12:30 p.m., National Institutes of Health, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, 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, 12:30 p.m. to 2 p.m.; open public hearing, 2 p.m. to 3 p.m., unless public participation does not last that long; Nancy T. Cherry or Denise A. Royster, 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), Vaccines and Related Biological Products Advisory Committee, code 12388. Please call the hotline for information concerning any possible changes.

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 by March 1, 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 required to make their comments.

Open committee discussion. The committee will discuss the influenza virus vaccine's formulation for 1997 and 1998.

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 the meeting(s) 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, 12420 Parklawn Dr., rm. 1–23, 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 (a)(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 12, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–4305 Filed 2–18–97; 11:00 am]

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[Docket No. 97N–0042]

Review of the Adverse Event Reporting System for Postmarketing Surveillance; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to provide the pharmaceutical industry and other interested persons with information on the plans, progress, and technical specifications developed under the reengineering of the Center for Drug Evaluation and Research's (CDER's) postmarketing surveillance program. The primary focus of the meeting will be the electronic submission of adverse drug reaction (ADR) reports under the new adverse event reporting system (AERS), which is currently under development as a major component of the reengineering effort.

DATES: The public meeting will be held on Monday, March 17, 1997, from 9:30 a.m. to 5 p.m. There is no registration fee for the meeting. Because space is limited, interested persons are encouraged to register by March 7, 1997.

ADDRESSES: The public meeting will held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Persons interested in attending should fax their registration to Robert Nelson at 301–480–2825. The facsimile should include the participant's name and title; organization name, if any; address; and telephone and fax numbers.

Three weeks prior to the public meeting, a copy of the meeting agenda will be available through CDER's Fax-on-Demand, 301–827–0577 or 800–342–