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Food and Drug Administration
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Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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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:

Nonprescription Drugs Advisory Committee

Date, time, and place. January 13, 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, 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.; 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 committee. The 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, in'formation, 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 pediatric dosing (use by children under 12 years of age) of over-the-counter (OTC) drug products. The committee will address topics such as: (1) What is the most preferred and practical basis for determining and labeling OTC systemic pediatric dosages, e.g., age, weight, height (length), body surface area, or a combination of these? (2) Is the dosing approach (adult-1 full dose, children 6 to 12- 1/2 adult dose, and children 2 to 6- 1/4 adult dose) currently being used for most OTC oral drugs an adequate method of dosing? (3) Should there be differences in systemic pediatric dosing ranges for specific ingredients or different classes of OTC drug products? If yes, for which specific ingredients or classes of products? (4) Should calibrated dosage devices be required for (specific or all) pediatric products? If yes, for which product(s) and how should they be calibrated (e.g., devices expressing dosage levels in teaspoon or milliliter units)? (5) What are the lowest limits (e.g., age, weight, etc.) for which specific dosing instructions should appear in OTC product labeling? Would these limits be different for certain classes of OTC drugs, such as internal analgesics, antihistamines, etc.?

Elsewhere in this issue of the Federal Register, the agency is announcing the availability of a summary information document for this meeting.

National Task Force on Aids Drug Development

Date, time, and place. January 19, 1995, 8:30 a.m., Holiday Inn-Bethesda, Versailles Ballrooms I through III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open task force discussion, 8:30 a.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Jean H. McKay or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF-12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0104, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602.

General functions of the task force. The task force identifies any barriers and provides creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers and provides options for the elimination of these barriers.

Open task force discussion. The task force will present, hear, and discuss issues on the barriers to acquired immunodeficiency syndrome (AIDS) drug development from the perspective of task force members, members of the Federal Government, and the public. The task force will determine how to proceed with overcoming the barriers to AIDS drug development

Agenda-Open public hearing. Interested persons may present

data, information, or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before January 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.

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. January 19 and 20, 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, January 19, 1995, 8:30 a.m. to 5 p.m.; open public hearing, January 20, 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 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, code 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 January 12, 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 hear presentations and discuss guidance criteria for the development of safe and effective medications for the treatment of obesity.

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. January 20, 1995, 9 a.m., 9200 Corporate Blvd., Main Conference Room, 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, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 4:30 p.m.; Michael G. Bazaral, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8610, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Anesthesiology and Respiratory Therapy Devices Panel, code 12624.

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 relating to the review of a premarket approval application supplement for a high frequency ventilator.

National Mammography Quality Assurance Advisory Committee
Date, time, and place. January 23, 24, and 25, 1995, 9 a.m., Dupont Plaza Hotel, Embassy Room, 1500 New Hampshire Ave. NW., Washington, DC. A limited number of overnight accommodations have been reserved at the Dupont Plaza Hotel. Attendees requiring overnight accommodations may contact the hotel at 202-483-6000 and reference the FDA committee meeting block. Reservations will be confirmed at the group rate based on availability.
Type of meeting and contact person. Open committee discussion, January 23, 1995, 9 a.m. to 5 p.m.; open committee discussion, January 24, 1995, 9 a.m. to 5 p.m.; open public hearing, January 25, 1995, 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.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3311, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.
General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.
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. The committee will discuss the draft final standards for accreditation bodies and the draft final standards for facilities. Specific topics to be discussed include: (1) Standards for accreditation bodies, (2) personnel standards, (3) quality assurance standards, (4) equipment standards, (5) medical audit and mammography reports, (6) consumer complaint mechanism, and (7) implant imaging.

Ophthalmic Devices Panel of the Medical Devices Advisory Committee
Date, time, and place. January 26, 1995, 8 a.m., 9200 Corporate Blvd., Main Conference Room, Rockville, MD. A limited number of overnight accommodations have been reserved at the Woodfin Suites, 1380 Piccard Dr., Rockville, MD. Attendees requiring overnight accommodations may contact the hotel at 301-590-9880 and reference the FDA Ophthalmic Devices 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 5 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053 or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396.

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 December 31, 1994, 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 relating to the development of guidance on clinical studies for extended wear contact lenses. There will also be a discussion of the multifocal intraocular lens guidance document and announcements concerning other intraocular implants and diagnostic and surgical devices updates. The committee will review and recommend the classification status for currently unclassified devices which may include plastic contact lens cases, vision tester trainers, epikeratophakia, intraocular lens folders, ophthalmic endoilluminators, refractive lasers, therapeutic corneal lasers, and scanning laser ophthalmoscopes.

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: December 14, 1994.

Linda A. Suydam,
Interim Deputy Commissioner for Operations.

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