1994 Federal Register (Vol 59) January - December
October
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First Match

Food and Drug Administration

NOTICES

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Food and Drug Administration

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.

MEETINGS: The following advisory committee meetinqs are announced:

Joint Meeting of the Food and Veterinary Medicine Advisory Committees
Date, time, and place. Novernber 2 and 3, 1994, 8:30 a.m., Howard Johnson Hotel-National Airport, Pentagon Ballroom, 2650 Jefferson Davis Hwy., Arlington, VA.
Type of meeting and contact person. Open committee discussion, November 2, 1994, 8:30 a.m. to 5:15 p.m.; open committee discussion, November 3, 1994, 8:30 a.m. to 8:45 a.m.; open public hearing, 8:45 a.m. to 9:45 a.m., unless public participation does not last that long; open committee discussion, 9:45 a.m. to 12:15 p.m.; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS-5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4727, or Catherine M. DeRoever, Advisory Committee Staff (HFS-22), 202-205-4251, FAX 202-205-4970.
General function of the committees. The Food Advisory Committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade. The Veterinary Medicine Advisory Committee reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal druqs, feeds, and devices for use in the treatment and prevention of animal disease

and increased animal production.

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 close of business October 25, 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. If necessary, comments may be limited to 5 minutes.

Open committee discussion. The joint committees will discuss possible future initiatives that impact on science and regulation in areas such as biotechnology, food safety and processing, compositionally enhanced foods, and food production and agriculture sustainability. The biotechnology discussion will focus on FDA's 1992 policy statement on foods derived from new plant varieties developed by new biotechnology methods. Also, because FDA is considering proposing a'premarket notification program, the committees will be asked to discuss procedures that FDA might use to become aware of a developer's intention to introduce such foods into commercial distribution. The agency will present examples of the applications for products currently approaching commercialization. In addition, the committees will be asked to consider proposed criteria that would identify concerns for which FDA might seek advisory committee assistance.

Joint Meeting of the Dermatologic Drugs and Anti-Infective Drugs Advisory Conunittees With Nonprescription Drugs Advisory Committee Representation

Date, time, and place. November 16, 1994, 8 a.m., Bethesda Holiday Inn, Versailles Ballroom, 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 5 p.m.; Ermona B. McGoodwin or Valerie M. Mealy, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

General function of the committees. The Dermatologic Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of dermatologic diseases. The Anti-Infective Drugs Advisory Committee reviews and evaluates data relating to the safety and effectiveness of marketed and investigational human drugs for use in infectious and ophthalmic disorders. 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 November 9, 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 jointly discuss the potential for development of antibiotic resistance with over-the-counter use of topical erythromycin in the treatment

of acne.

Anti-Infective Drugs Advisory Committee

Date, time, and place. November 17, 1994, 8:30 a.m., Bethesda Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

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 5 p.m.; Ermona B. McGoodwin or Mary Elizabeth Donahue, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

General function of the committee. The committee reviews and evaluates data relating to the safety and effectiveness of marketed and investigational human drugs for use in infectious and ophthalmic 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 November 9, 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 the validity of endoscopically-obtained maxillary sinus specimens versus antral puncture for the microbiological diagnosis of sinusitis.

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: October 14, 1994

Linda A. Suydam,
Interim Deputy Commissioner for Operations.

[FR Doc. 94-25945 Filed 10-17-94; 8:45 am]
BILLING CODE 4160-01-F

The Contents entry for this article reads as follows:

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