1993 Federal Register (Vol 58) January - December
March
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 meetings are announced:

OTC Drugs Advisory Committeee
Date, time, and place. April **8** and 9, **1993, 8** a.m., Parklawn Bldg., conference rooms D and E, **5600** Fishers Lane, Rockville, MD.
Type of meeting and contact person. Open committee discussion, April **8, 1993, 8** a.m. to **1** p.m.; closed committee deliberations, **1** p.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3 p.m., unless public participation does not last that long; open committee discussion, **3** p.m. to **5** p.m.; open committee discussion, April **9, 1993, 8** a.m. to **1** p.m., open public hearing, **1** p.m. to 1:30 p.m., unless public participation does not last that long; open committee discussion, 1:30 p.m. to **5** p.m.; Mae Brooks or Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, **5600** Fishers Lane, Rockville, MD **20857, 301-443-4695.**
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, 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 April

1, 1993, 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 April 8, 1993, the committee will discuss the role and appropriate dosage ranges of caffeine as an adjuvant in analgesic drug products. The agency's evaluation of data concerning caffeine as an adjuvant in analgesic drug products was discussed in comments 91 and 92 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products published in the Federal Register of November 16, 1988 (53 FR 46204 at 46244 and 46245). Additional data submitted since that time will be considered by the committee. The committee's discussion and recommendations on caffeine will be considered by the agency in its preparation of a final monograph for OTC internal analgesic drug products. On April 9, 1993, the committee will discuss portions of a citizen's petition related to continued marketing of OTC antidiarrheal drug products containing attapulgite, kaolin, and pectin. The committee will also discuss the role of oral rehydration therapy in the treatment of diarrhea. The petition under docket number 93P-0011 is available for public examination at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The agency's evaluation of data concerning these ingredients was discussed in comments 15, 23, and 24 of the tentative final monograph for OTC antidiarrheal drug products published in the Federal Register of April 30, 1986 (51 FR 16138 at 16142 and 16145). Additional data submitted since that time will be considered by the committee. The committee's discussion and recommendations on these ingredients will be considered by the agency in its preparation of a final monograph for OTC antidiarrheal drug products.

Closed committee deliberations. On April 8, 1993, the committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 12, 13, and 14, 1993, 8:30 a.m., Hubert H. Humphrey Bldg., rms. 503-529A, 200 Independence Ave. SW., Washington, DC.

Type of meeting and contact person. Open public hearing, April 12, 1993, 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 presentation of data, 3 p.m. to 4 p.m.; open public hearing, April 13, 1993, 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 presentation of data, 3 p.m. to 4 p.m.; open public hearing, April 14, 1993, 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 presentation of data, 3 p.m. to 4 p.m.; closed committee deliberations, 4 p.m. to 4:30 p.m.; Wolf Sapirstein, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1205.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed

and investigational devices and makes recommendation 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 April 1, 1993, 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 premarket approval applications for one or more implantable cardioverter defibrillator devices, prosthetic cardiac valves, and interventional cardiology devices.

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

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

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 29 and 30, 1993, 9 a.m., Bethesda Ramada Inn, Ambassador Room, 8400 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, April 29, 1993, 9 a.m. to 10 a.m., unless public participation does not last that long; closed presentation of data, 10 a.m. to 11 a.m.; closed committee deliberations, 11 a.m. to 1 p.m.; open committee discussion, 1 p.m. to 5 p.m.; open public hearing, April 30, 1993, 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.; Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1180.

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 April 15, 1993, 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 home uterine activity monitors (HUAM's) used for the early detection of preterm labor. The committee will review and make recommendations on premarket approval applications for HUAM's. The committee will also review and discuss draft guidelines for testing HUAM's.

Closed presentation of data. The committee will discuss trade secret and/or confidential commercial information regarding home uterine activity monitors. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. The committee will discuss trade secret and/or confidential commercial information regarding home uterine activity monitors. 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, with the concurrence of the Chief Counsel, 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, notably deliberative session 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: March 15, 1993

Jane E. Henney,
Deputy Commissioner for Operations.

[FR Doc. 93-6531 Filed 3-22-93; 8:45 am]
BILLING CODE 4160-01-F