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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 meetings are announced:

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. December 16, 1992, 8:30 a.m., Conference rms. G and H, Parklawn Bldg., 5600 Fishers Lane, Rockville, 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 4 p.m.; closed presentation of data, 4 p.m. to 4:30 p.m.; Mark D. Kramer, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1194.

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 November 30, 1992, 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 design of clinical studies used to investigate the safety and effectiveness of devices used for the extracorporeal removal of LDL (low-density lipoprotein) cholesterol, and possibly a

premarket approval application supplement for an extracorporeal shockwave lithotripter with a new indication for the treatment of middle and lower ureteral stones.

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

Over-the-counter (OTC) Drugs Advisory Committee

Date, time, and place. December 16 and 17, 1992, 8 a.m., Holiday Inn-Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, December 16, 1992, 8 a.m. to 4 p.m.; open public hearing, 4 p.m. to 4:30 p.m., unless public participation does not last that long; closed committee deliberations, 4:30 p.m. to 5:30 p.m.; open committee discussion, December 17, 1992, 8 a.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 4 p.m.; 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 December 8, 1992, 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 December 16, 1992, the committee will hear and discuss orientation presentations on the role of the advisory committee in the regulation of OTC or nonprescription drug products. On December 17, 1992, the committee will discuss the presence of alcohol in oral OTC drug products intended for ingestion by adults and children. The discussion will include the types of products, the pharmaceutical role of alcohol, possible content limitations, and nonalcohol formulation alternatives. The agency's views on alcohol in cough-cold drug products for children and recommendations made by the American Academy of Pediatrics were stated in comment 16 of the tentative final monograph for OTC cough-cold combination drug products published in the Federal Register of August 12, 1988 (53 FR 30522 at 30528 and 30529). The committee's discussion and recommendations on alcohol may be considered by the agency in its preparation of a final monograph for OTC cough-cold combination or other OTC drug products.

Closed committee deliberations. The committee will discuss trade secret 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)).

Blood Products Advisory Committee

Date, time, and place. December 17 and 18, 1992, 8:30 a.m.,

Parklawn Bldg., Conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, December 17, 1992, 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, December 18, 1992, 8:30 a.m. to 10:15 a.m.; closed committee deliberations, 10:15 a.m. to 10:45 a.m., open committee discussion, 10:45 a.m. to 4 p.m.; Linda A. Smallwood, Division of Transfusion Science, Center for Biologics Evaluation and Research (HFB-902), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-227-6700.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products 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 December 11, 1992, 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 December 17, 1992, the committee will review data and will discuss the topic of irradiated blood and blood components to develop criteria for licensure. On December 18, 1992, the committee will: (1) Review product license applications for HIV-1 and HIV-2 combination tests containing env (only) peptides, (2) review the premarket approval application for the Epitope Orasure HIV-1 test kit for testing of oral fluid samples, and (3) hear an overview of the Orphan Drug Act.

Closed committee deliberations. The committee will discuss confidential and/or commercial information relevant to the product license applications for HIV-1 and HIV-2 combination tests. 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 will be available 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 will be available 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: November 19, 1992.

David A. Kessler,
Commissioner of Food and Drugs.

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