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Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Joint Subconunittee Meeting of the Nonprescription Drugs Advisory Committee and Arthr tis Advisory Committee on Over-the-Counter Internal Analgesic, Antipyretic, and Antirheumatic Drug Products

Date, tine, and place. September 8 and 9, 1994, 8:30 a.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, September 8, 1994, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; open conunittee discussion, September 9, 1994, 8:30 a.m. to 4 p.m., open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; 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 committees. 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. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investiqational human drugs for use in arthritic conditions.

Agenda-Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the joint subcommittee. Those desiring to make formal presentations should notify the contact person before

August 15, 1994, and submit a brief statement of the general nature of the information or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their comments. In a subsequent issue of the Federal Register, FDA will publish a notice announcing the availability of background information.

Open committee discussion. On September 8 and 9, 1994, the joint subcommittee will discuss effectiveness data requirements and proposed labeling indications for OTC analgesic drug products. The joint subcommittee will address topics such as: (1) Data requirements to support specific types of indications for OTC analgesic drug products; (2) recommendations for labeling indications for OTC analgesics; and (3) the current state of scientific knowledge in the areas of pain receptors, mechanism(s) of pain perception, and the basis for response to analgesic drug classes.

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: July 5, 1994

Linda A. Suydam,
Interim Deputy Commissioner for Operations.

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