

1996 Federal Register (Vol 61) January - December

May

Vol. 61 No. 84 Tuesday, April 30, 1996

Food and Drug Administration

Meetings: Advisory committees, panels, etc., 19076

*** First Match**

Food and Drug Administration

NOTICES

Meetings: Advisory committees, panels, etc., 19076

Vol. 61 No. 84 Tuesday, April 30, 1996 p 19076 (Notice) 1/155

Food and Drug Administration

Advisory Conunittee; 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.

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.

MEETING: The following advisory committee meeting is announced:

Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee

Date, time, and place. June 6 and 7, 1996, 8 a.m., Holiday Inn-Gaithersburg, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, June 6, 1996, 8 a.m. to 11 a.m., unless public participation

does not last that long; open committee discussion, 11 a.m. to 5 p.m.; open public hearing, June 7, 1996, 8 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; Jeanne L. Rippere or Stephanie Mason, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 1600 Rockville Pike, Rockville, MD 20857, 301-827-2244, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Dental Products Panel of the Medical Devices Advisory Committee, code 12518. Please call the hotline for information concerning any possible changes.

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.

-The Dental Products Panel of the Medical Devices Advisory Committee functions at times as a nonprescription drug advisory panel. As such, the panel reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use, the adequacy of their labeling,, and advises the Commissioner of Food and Drugs on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

Agenda-Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Those desiring to make formal presentations should notify the contact person before May 24, 1996, 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 subcommittee discussion. On June 6, 1996, the subcommittee will continue its discussion concerning the alcohol content of oral health care mouthwash drug products begun at its June 28 and 29, 1994, meeting. On June 7, 1996, the subcommittee will continue its discussion of hydrogen peroxide, sodium bicarbonate, the combination of hydrogen peroxide and sodium bicarbonate, and sanguinaria. The subcommittee will also begin a discussion of sodium lauryl sulfate. For further information on the agenda of this meeting, see the background document published elsewhere in this issue of the Federal Register.

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.

---- page << 190772 ----

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, 5600 Fishers Lane, rm. 12A-16, 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, 12420 Parklawn Dr., rm. 1-23, 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: April 24, 1996

Michael A. Friedman,
Deputy Commissioner for Operations.

[FR Doc. 96-10780 Filed 4-26-96; 2:36 pm]
BILLING CODE 4160-01-F

.....
The Contents entry for this article reads as follows:

Meetings:
Advisory committees, panels, etc., 19076