

the criteria document, or reserve overnight accommodations at the Drawbridge Inn, should respond by May 10, 1996, to Kellie Wilson, NIOSH, 4676 Columbia Parkway, M/S C-34, Cincinnati, Ohio 45226, telephone 513/533-8362, fax 513/533-8588, e-mail address: kmp0@NIOSDT1.em.cdc.gov. Information may also be obtained by calling 1-800-35-NIOSH or by the Internet NIOSH Homepage: <http://www.cdc.gov/niosh/homepage.html>.

Dated: April 23, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-10601 Filed 4-29-96; 8:45 am]

BILLING CODE 4160-19-M

Food and Drug Administration

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.

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.

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

[Docket No. 81N-033P]

Background Document for the Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a background document for the meeting of the Dental Drug Products Panel Plaque Subcommittee of the Medical Devices Advisory Committee (the subcommittee). This meeting is announced elsewhere in this issue of the Federal Register, and it is scheduled for June 6 and 7, 1996. This background document is being taken to ensure that all interested parties are aware of the subcommittee's concern regarding the relationship, if any, of alcohol-containing mouthwashes and oral cancer and the development of studies to investigate the relationship. This relationship will be the subject of

the subcommittee's discussion on June 6, 1996.

DATES: Written comments or data should be submitted by May 10, 1996, in order to be considered for discussion at the June 6, 1996, subcommittee meeting.

ADDRESSES: Single copies of the background briefing document may be requested in writing from the Freedom of Information Staff (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, at a cost of 10 cents per page. Requests should be identified with the docket number found in brackets in the heading of this document. The background briefing document is available for public examination at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Comments and data should be identified with the docket number listed above. Individuals or groups wishing to submit data or comments relevant to alcohol-containing mouthwashes should send them to the Dockets Management Branch (HFA-305), 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Three copies of written comments should be submitted, except that individuals may submit one copy. The comments and data received are available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

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.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the Federal Register, FDA announced that a meeting of the Dental Drug Products Panel Plaque Subcommittee will be held on June 6 and 7, 1996. The purpose of the meeting scheduled for June 6, 1996, is to continue the subcommittee's discussion concerning the alcohol content of oral health care mouthwash drug products begun at its meeting of June 28 and 29, 1994. After evaluating the available data, the subcommittee concluded that it should meet in a workshop environment with representatives of the National Cancer Institute, the National Institute of Dental Research, other professional groups, the agency, and industry to address any new information regarding a causal relationship between alcohol-containing mouthwashes and oral cancer. The subcommittee recommended that this

workshop should address the development of sound scientific studies to determine the relationship, if any, between alcohol-containing mouthwash products and cancer of the oral cavity.

FDA has established a docket number (81N-033P) as a public record of the comments, views, and other information submitted to the agency from interested persons and organizations regarding alcohol in oral health care mouthwash drug products. After publication of the subcommittee's report, this docket will be the repository of all data and information collected by the agency for the over-the-counter (OTC) antiplaque/antigingivitis drug review, but currently it will contain only those comments and data that are not confidential under the OTC drug review. (See the request for data and information on dental and oral health care drug products for antiplaque use published in the Federal Register of September 19, 1990 (55 FR 38560 at 38562).) Copies of the background briefing documents have been placed in this docket and may be seen in the Dockets Management Branch (address above) or obtained from the agency's Freedom of Information Staff (address above). Copies of the background briefing document will also be available at the committee meeting.

Dated: April 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-10781 Filed 4-26-96; 2:36 pm]

BILLING CODE 4160-01-F

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice is publishing the following summaries of proposed collections for public comment. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed