This notice is issued under section 10(a)(1) and (a)(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 16, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–10477 Filed 4–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of the Committee: Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee, code 12518.

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 drugs advisory panel. As such, the committee 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 issuance of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

Date and Time: The meeting will be held on May 8 and 9, 1997, 8:30 a.m. to 5 p.m. Open public hearing portions are scheduled from 8:30 a.m. to 12 m. on May 8, 1997, and from 8:30 a.m. to 12 m. on May 9, 1997.

Location: Ramada Inn—Bethesda, Ambassador Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Andrea G. Neal or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 8, 1997, the subcommittee will discuss the safety of the individual ingredients menthol, thymol, methyl salicylate, and eucalyptol, and continue its discussion of the effectiveness of these ingredients. The subcommittee will also discuss zinc citrate. In addition, there will be continued discussion and/or summaries and voting on the ingredients cetylpyridinium chloride, Microdent, sodium lauryl sulfate, and C31G-Therasol® .

On May 9, 1997, the subcommittee will discuss the safety and effectiveness of the combination of hydrogen peroxide and povidone iodine, and the effectiveness of the combination of hydrogen peroxide, sodium citrate, zinc chloride, and sodium lauryl sulfate. There will also be continued discussion and/or summaries and voting on the ingredients xylitol, sodium bicarbonate, and the combination of hydrogen peroxide and sodium bicarbonate. In addition, the subcommittee will discuss general recommendations for antiplaque combination ingredients.

Procedure: The meeting is open to the public. Interested persons may present data, information, or views, orally, or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 30, 1997. Those desiring to make formal presentations should notify the contact person before April 30, 1997, 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 requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the May 8 and 9, 1997, Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–10479 Filed 4–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0164]

Positron Emission Tomography Drug Products; Draft Guidance for Industry on Content and Format of an Abbreviated New Drug Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products.'' This draft guidance is intended to assist applicants who wish to submit an ANDA for Fludeoxyglucose F18 Injection. The draft guidance is one of several topics to be discussed at an April 28, 1997, FDA workshop on PET radiopharmaceutical drug products. The agency is requesting comments on this draft guidance.

DATES: Written comments may be submitted on the draft guidance document by June 28, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments will be available for public examination in the Dockets