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

Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Peter Rickman, Center for Drug Evaluation and Research (HFD–615), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0315.

SUPPLEMENTARY INFORMATION: 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.'' PET is a medical imaging modality used to assess the body's biochemical processes. Radionuclides are manufactured into PET radiopharmaceutical drug products that are administered to patients for medical imaging. The images of the body's biochemical processes are then evaluated, generally for diagnostic purposes.

Under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), ANDA's may be submitted for drug products that are the same as a listed drug, i.e., identical in active ingredient(s), dosage form, strength, route of administration and conditions of use, except for those uses for which approval cannot be granted because of exclusivity, or for which an existing patent may be omitted (21 CFR 314.92). Because a new drug application (NDA) for Fludeoxyglucose F18 Injection (NDA 20–306) was approved on August 19, 1994, for the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures, ANDA's may be submitted for drug products that are the same as this reference listed drug product and for the same use. The purpose of the draft guidance document is to assist applicants who wish to submit an ANDA for Fludeoxyglucose F18 Injection. The draft guidance is one of several issues to be discussed at an April 28, 1997, FDA workshop on PET radiopharmaceutical drug products. The workshop, which will be held in Rockville, MD, was announced in the **Federal Register** on March 14, 1997 (62 FR 12218). Other issues to be discussed at the workshop include: Registration and listing requirements, chemistry and manufacturing controls, sterility assurance, bioequivalence requirements, and labeling.

This guidance document represents the agency's current thinking on the content and format of an ANDA for PET radiopharmaceutical drug products. It does not create or confer any rights for, or on, any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance document to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments also may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this draft guidance is available on the Internet using the World Wide Web (http://www.fda.gov/cder/guidance.htm).

Dated: April 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–10542 Filed 4–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds for Planning Grants To Establish Comprehensive HIV Primary Health Care Services; The Ryan White Comprehensive AIDS Resources Emergency Act of 1990, as Amended by the Ryan White CARE Act Amendments of 1996

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Availability of Grants to Support Planning Activities To Establish Comprehensive Primary Health Care Services with Respect to Human Immunodeficiency Virus (HIV) Disease.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1997 discretionary grants to support communities and health care service entities in their preparations to provide a high quality and broad, comprehensive scope of primary health care services for people in underserved areas who are living with HIV or at risk of infection. The Ryan White Title III HIV Planning Grants are intended to assist health care service entities to qualify for grant support under the Ryan White Title III Early Intervention Services Program.

These grants are awarded under the provisions of Part C of Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White CARE Act Amendments of 1996, Public Law 104–146 (42 U.S.C. 300ff–51—300ff–67).

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting health priorities. This grant program is related to the objectives cited for special populations, particularly people with low income, minorities, and the disabled, which constitute a significant portion of the homeless population. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017–001–00474–0) or *Healthy People 2000* (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (telephone 202–783–3238).

PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

DUE DATE: Applications are due on May 23, 1997. Applications will be considered to have met the deadline if they are: (1) received on or before the deadline date; or (2) postmarked on or before the established deadline date and received in time for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailing. Applications postmarked after the announced closing date will not be considered for funding.

ADDRESSES: Application kits (Form PHS 5161–1) with revised face sheet DHHS Form 424, as approved by the Office of Management and Budget under control number 0937–0189 may be obtained from, and completed applications should be mailed to HRSA Grants Application Center, 40 West Gude Drive, Suite 100, Rockville, MD 20850 (telephone: 1–888–300–4772). The Bureau of Primary Health Care's Office of Grants Management can also provide assistance on business management issues, and can be reached at 4350 East-