committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On June 20, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before April 14, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 16, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–6409 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97N–0083]

Abbreviated New Drug Applications; Positron Emission Tomography Radiopharmaceuticals; Notice of a Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to provide information to the positron emission tomography (PET) radiopharmaceutical industry on submitting abbreviated new drug applications (ANDA's) and other regulatory issues affecting PET radiopharmaceutical drug products. The workshop will provide guidance on topics such as ANDA regulatory requirements, registration and listing requirements, chemistry and manufacturing controls, sterility assurance, bioequivalence requirements, and labeling. An agenda and materials to be discussed at the workshop will be available before the workshop.

DATES: The workshop will be held on Monday, April 28, 1997, from 8 a.m. to 5 p.m. Because space is limited, interested persons are encouraged to register as soon as possible. Preregistration will be accepted through April 18, 1997. There is no registration fee for the workshop. The administrative docket will remain open until June 27, 1997, to receive written comments, data, information, or views on the workshop and materials distributed at the workshop.

ADDRESSES: The workshop will be held at the Parklawn Bldg., 5600 Fishers Lane, conference rm. D, Rockville, MD 20857. Persons interested in attending should pre-register by faxing their name, title, organization name if any, address, telephone and fax numbers to the contact person. Registrants' fax numbers should be provided, so that registration can be confirmed by return fax.

Before the workshop, the agenda and materials to be discussed at the workshop will be available via the Internet using the World Wide Web (WWW). To connect to the Center for Drug Evaluation and Research (CDER) Home Page, type http://www.fda.gov/cder and go to the ''What's Happening'' section. A transcript of the workshop will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 business days after the workshop at a cost of 10 cents per page.

Written comments on the workshop or materials discussed at the workshop can be submitted until June 27, 1997, to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of 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 notice. Received comments may be viewed at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Susan C. Lange, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–160), 5600 Fishers Lane, Rockville, MD 20857, 301–443–0260, FAX 301–594–0746.

SUPPLEMENTARY INFORMATION:

I. Background

PET is a diagnostic imaging modality consisting of onsite production of radionuclides that are usually intravenously injected into patients for diagnostic purposes. The potential usefulness of a PET radiopharmaceutical is based upon the product's interaction with a biochemical process in the body.

Over the last 20 years, there has been increasingly widespread commercial use of a growing number of PET radiopharmaceuticals. Having considered the available information, including that presented to the agency at a March 1993 hearing and in written materials, in the Federal Register of February 27, 1995 (60 FR 10593), FDA provided additional notice and guidance to the industry stating how the agency would apply its regulatory authority to PET drug products.

Since the approval of one new drug application for F–18 FDG, PET drug product manufacturers have sought information on the submission of ANDA's. Details of the ANDA submission process will be discussed at the workshop. Other topics to be addressed include registration and listing requirements, chemistry and manufacturing controls, sterility assurance, bioequivalence requirements, labeling, and compliance with current

good manufacturing practice regulations and other regulatory requirements. Materials providing guidance on ANDA submissions and related topics will also be discussed at the workshop.

Dated: March 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6410 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Mechanism

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service (PHS) Act, ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of HHS in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed that amount determined under a statutory formula.

The purpose of this notice is to request comments on the proposal of a rebate process for State AIDS Drug Assistance Programs (ADAPs) receiving funds under Title XXVI of the PHS Act.

DATES: The public is invited to submit comments on the proposed rebate process by April 14, 1997. After consideration of comments submitted, the Secretary will issue the final guideline.

ADDRESS: Comments should be submitted to: Annette Byrne, R. Ph., M.S., Director, Office of Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, MD 20814, Phone (301) 594–4353; FAX (301) 594–4982.

FOR FURTHER INFORMATION CONTACT: Robert Staley, R. Ph., Senior Program Manager, Office of Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, MD 20814, Phone (301) 594–4353; Fax (301) 594–4982.

SUPPLEMENTARY INFORMATION: Section 340B requires manufacturers, as a condition for the receipt of Medicaid matching funds with respect to their covered outpatient drugs, to charge participating entities no more than a ceiling price for such drugs. This price is determined by reducing the average manufacturer price of the drug by a rebate percentage. Entities eligible to access section 340B pricing (covered entities) include certain PHS grantees (e.g., federally-qualified health centers, certain family planning projects, AIDS assistance programs, black lung clinics, hemophilia treatment centers, Native Hawaiian health centers, and centers that treat sexually-transmitted disease and/or tuberculosis) and certain disproportionate share hospitals.

Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount system) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate system). Section 340B(a)(1) of the PHS Act provides that the amount to be paid to the manufacturers for covered drugs takes ''into account any rebate or discount, as provided by the Secretary * * * '' Further, section 340B does not specify whether entities should receive the section 340B pricing ''through a point of purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS drug assistance programs * * * [T]he Secretary of HHS * * * will use the mechanism that is the most effective and most efficient * * * ''. H.R. Rep. No 102–384, 102d Cong., 2d Sess., pt. 2, at 16 (1992).

Initially, HRSA guidance for the section 340B program described only a discount process. Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.

Although the discount system is functioning successfully for most covered entities, most ADAPs have drug purchasing systems that have prevented their participation in the section 340B discount program. The use of a rebate mechanism (in addition to the discount mechanism) should allow these groups to access section 340B pricing.

The HRSA recognizes rebates obtained by the State ADAPs as a method of accessing the section 340B discount price. The rebate for covered outpatient drugs should be equal to or greater than the section 340B discount at the time of purchase price. State ADAPs wishing technical assistance in developing a rebate program should contact HRSA's Office of Drug Pricing at (301) 594–4353 or (800) 628–6297.

The HRSA is sensitive to concerns about diversion of covered drugs to individuals who are not patients of the covered entities. Guidelines have been issued to minimize this potential, and manufacturers have available to them specified remedies if they believe diversion has occurred. The HRSA believes that these guidelines and remedies will apply fully to drugs purchased under a rebate procedure and that instituting rebates will not increase the potential for diversion.

Dated: March 10, 1997.

Ciro V. Sumaya,

Administrator.

[FR Doc. 97–6414 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4200–N–34]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: May 13, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451–7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Daniel Kahn, telephone number (202) 708–2121 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the