on identical items from 10 or more public respondents must be approved by the Office of Management and Budget (OMB) and must display a valid OMB control number and expiration date.

In accordance with the Paperwork Reduction Act, in the Federal Register of February 4, 1994 (59 FR 5436), a notice announced the proposed revision of FDA Form 3210 Application For Establishment License for Manufacture of Biological Products. OMB approval for the revised FDA Form 3210 was obtained on April 30, 1994, and given OMB approval number 0910–0124; expiration date April 30, 1997.

Dated: February 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–4766 Filed 2–24–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0042]

Drug Export; OGEN (Piperazine Oestrone Sulfate) 0.625 Milligram (mg), 1.25 mg, and 2.5 mg Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Abbott Laboratories has filed an application requesting approval for the export of the human drug OGEN (piperazine oestrone sulfate) 0.625 milligram (mg), 1.25 mg, and 2.5 mg Tablets to Australia.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Abbott Laboratories, One Abbott Park Rd., Abbott Park, IL 60064–3500, has filed an application requesting approval for the export of the human drug OGEN (piperazine oestrone sulfate) 0.625 mg, 1.25 mg, and 2.5 mg Tablets to Australia. This product is indicated for replacement therapy of oestrogen deficiency in female hypogonadism, amenorrhoea, female castration, primary ovarian failure, and in the management of menopausal syndrome, senile vaginitis, kraurosis vulvae with or without pruritus, and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology. The firm has new drug application approval for OGEN (piperazine oestrone sulfate) in the above dosage strengths using a different manufacturing process. The application was received and filed in the Center for Drug Evaluation and Research on October 31, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 9, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: February 9, 1995.

Edward Miracco,

Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–4768 Filed 2–24–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94D–0422]

Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guideline entitled ''Draft Guideline on the Manufacture of Positron Emission Tomographic (PET) Drug Products'' prepared by FDA's Center for Drug Evaluation and Research (CDER). The draft guideline is intended to assist persons in determining whether certain manufacturing practices, procedures, and facilities used in the small-scale production of liquid injectable radiopharmaceutical drug products used for positron emission tomography (PET radiopharmaceuticals) are in compliance with FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

DATES: Written comments by May 30, 1995.

ADDRESSES: Submit written requests for single copies of the draft guideline entitled ''Draft Guideline on the Manufacture of Positron Emission Tomographic (PET) Drug Products'' to the CDER Executive Secretariat Staff (HFD–8), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: John W. Levchuk, Center for Drug Evaluation and Research (HFD–322), Food and

Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0095.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guideline entitled ''Draft Guideline on the Manufacture of Positron Emission Tomographic (PET) Drug Products.'' PET is a diagnostic imaging modality consisting of onsite production of radionuclides that are 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. For example, the product may be substituted for glucose in anaerobic glycolysis, theoretically localizing in ischemic tissues where glucose metabolism is the predominant energy source (epileptic foci, acute vascular insufficiency states).

The manufacture of PET radiopharmaceuticals consists of a process that takes place within a few hours. A target material is irradiated by a cyclotron; chemical synthesis takes place in a programmed, automated apparatus; and the final solution is compounded and filled. The biological distribution of a PET radiopharmaceutical in the body is monitored by a positron tomograph, or PET scanner, which detects the photons emitted as a result of the radioactive decay of the PET radiopharmaceutical. Because of their short half-lives, PET radiopharmaceuticals are characteristically manufactured in PET centers in response to daily demand for relatively few patients. PET centers are usually located in medical centers.

PET manufacturing procedures differ in a number of important ways from those associated with the manufacture of conventional drug products, mainly due to the short half-lives involved:

1. A maximum of only a few lots are manufactured per day, with one lot equaling one multiple-dose vial. This is administered to the patient usually within a matter of hours. Prolonged manufacturing time significantly erodes the useful clinical life of PET radiopharmaceuticals.

2. The quantities of radioactive active ingredients contained in each lot of a PET radiopharmaceutical generally vary from nanogram to milligram amounts, depending upon various product parameters.

3. Because one lot equals one multiple-dose vial containing a homogeneous solution of a PET product (e.g., 2-deoxy-2 [^{18}F]fluoro-D-glucose), results from end-product testing of samples drawn from the single vial have the maximum possible probability of being representative of all the doses administered to patients from that vial, barring sampling or testing error.

4. An entire lot may be administered to one or several patients, depending upon the activity remaining in the container at the time of administration. Consequently, the administration of the entire quantity of a lot to a single patient should be anticipated for every lot manufactured. This is an important consideration when establishing the testing limits for certain attributes such as endotoxins and impurities.

5. PET radiopharmaceuticals usually do not enter a general drug distribution chain. Rather, the entire lot (one vial) is usually distributed directly from the PET center either to a single medical department or physician for administration to patients or to a radiopharmacy for dispensing. Distribution may occur to other centers when the geographic proximity will allow for distribution and use within the drug product's half-life parameters.

Conventional compliance with CGMP regulations would be expected where special characteristics such as those listed above do not exist; for example, in large-scale PET operations. Elsewhere in this issue of the Federal Register, FDA is publishing (1) A proposed rule that would authorize the Director, CDER, or the Director, Office of Compliance, CDER, to approve exceptions or alternatives to the application of the provisions of 21 CFR part 211 to the manufacture of PET radiopharmaceuticals, and (2) a notice of a public workshop and FDA guidance on the regulation of PET radiopharmaceuticals.

The guideline entitled ''Draft Guideline on the Manufacture of Positron Emission Tomographic (PET) Drug Products'' discusses, generally, quality control units, personnel qualifications, staffing, buildings and facilities, equipment, components, containers, closures, production and process controls, packaging and labeling control, holding and distribution, testing and release for distribution, stability testing and expiration dating, reserve samples, yields, second-person checks, and reports and records.

FDA is making this draft guideline available for public comment before issuing a final guideline. If, following the receipt of comments, the agency concludes that the draft guideline will assist persons in determining whether manufacturing practices used in the small-scale production of liquid injectable PET radiopharmaceuticals are in compliance with FDA's CGMP regulations for finished pharmaceuticals, then the agency will prepare a final guideline and will announce its availability in the Federal Register.

Guidelines are generally issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to state procedures or standards of general applicability that are not legal requirements but are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, if the agency makes the guideline final, the guideline would not be issued under the authority of current § 10.90(b), and would not create or confer any rights, privileges, or benefits for or on any person, nor would it operate to bind FDA in any way.

Interested persons may, on or before May 30, 1995, submit to the Dockets Management Branch (address above) written comments on the draft guideline. 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 guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–4689 Filed 2–24–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0005]

Regulation of Positron Emission TomographyRadiopharmaceutical Drug Products; Guidance; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing guidance on the regulation of positron emission tomography (PET) radiopharmaceutical drug products. FDA has developed this guidance to make clear the regulatory approach designed to help ensure the safe and effective use of these products. The agency is also announcing a public workshop to facilitate an understanding of regulatory requirements regarding these products.

DATES: The public workshop will be held on March 21, 1995, 8:30 a.m. to 4 p.m. Registration will be between 8 a.m. and 8:30 a.m. Due to limited space, interested persons must preregister before March 7, 1995, by telephoning