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