

Receipt of new/revised/supplementary/competitive renewal applications	Initial review	Secondary review	Earliest award date
May 1, 1995 ...	June ..	July ...	Aug. 1, 1995.

FUTURE RECEIPT DATES ARE AS FOLLOWS:

Receipt of new/revised/supplementary/competitive renewal applications	Initial review	Secondary review	Earliest award date
April	June ..	July ...	Aug.

Where to Obtain Additional Information

All application procedures and guidelines are contained within this program announcement. Business management technical assistance may be obtained from Maggie Slay, Grants Management Specialist, Centers for Disease Control and Prevention (CDC), 255 East Paces, Ferry Road, NE., Mailstop E13, Atlanta, GA 30305, telephone (404) 842-6797. Programmatic technical assistance may be obtained from Tom Voglesonger, Program Manager, Injury Control Research Centers, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K58, Atlanta, GA 30341-3724, telephone (404) 488-4265.

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, DC 20402-9325, telephone (202) 783-3238.

Dated: February 21, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-4684 Filed 2-24-95; 8:45 am]

BILLING CODE 4163-18-P

Food and Drug Administration

[Docket No. 94D-0386]

Revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94). This form replaces the previous edition of FDA Form 3210 (12/88). FDA Form 3210 is used by manufacturers to apply for licensure of a facility for the manufacture of biological products regulated under the Public Health Service Act. The form has been revised because of inadequacies in the previous form that resulted in requests by the agency for supplemental information. The revised form is intended to shorten review time and decrease expenditure of resources for both the agency and industry.

DATES: FDA will continue to accept submissions using the previous Form 3210 (12/88) until August 28, 1995.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

ADDRESSES: Submit written requests for single copies of the revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94) to Division of Congressional and Public Affairs (HFM-11), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-1800. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The form may also be obtained by calling the CBER FAX Information System at 301-594-1939 from a FAX machine with a touch tone phone attached or built in. FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94) is available for public examination in the Dockets Managements Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD

20857, between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: FDA is making available revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94). The form was revised due to inadequacies in the old form which made the application review process cumbersome and difficult for both the agency and industry. In the past, the review process was often significantly lengthened because of requests by the agency for supplemental information from the manufacturer in order to ensure the safety, purity, potency, and efficacy of manufactured biological products. The revised form details more specifically the information that is required for establishment licensure. FDA believes that the revised form will expedite the review process by reducing the need for supplemental information requests and responses.

The revised form solicits information from the manufacturer in the following areas: (1) General information (names and addresses); (2) water systems; (3) heating ventilation and air conditioning systems; (4) raw materials and ancillary facilities; (5) source materials; (6) propagation of host systems; (7) intermediate processing; (8) formulation and final product preparation; (9) computer systems; (10) support areas; (11) quality control areas; (12) animal facilities for testing; (13) animal facilities for production; (14) calibration and validation; and (15) records.

In addition, the revised form also requires the following information to be submitted: A description of the lot numbering system, an organizational chart, an environmental assessment report, written agreements, curriculum vitae for key manufacturing and responsible personnel, and an overview of the current good manufacturing practices (CGMP) training program. A comments section is provided on the revised form for additional information that the manufacturer deems to be appropriate but may not be covered under other sections.

Manufacturers preparing to submit applications for establishment licensure should now utilize the revised (4/94) form. FDA will continue to accept submissions using the previous (12/88) form until August 28, 1995. Because the old form does not address specific questions and issues that are present on the revised form, additional review cycles should be anticipated when using the previous form.

Under the Paperwork Reduction Act of 1980 (Pub. L. 96-511) all forms requesting a collection of information

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