

application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than May 1, 1995.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Buerge Bancshares, Inc.*, Joplin, Missouri; to acquire 100 percent of the voting shares of Peoples State Bank, Claremore, Oklahoma.

Board of Governors of the Federal Reserve System, March 31, 1995.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 95-8407 Filed 4-5-95; 8:45 am]

BILLING CODE 6210-01-F

GENERAL SERVICES ADMINISTRATION

Public Buildings Service; Proposed Port of Entry, Located at Pacific Highway, Blaine, Whatcom County, WA; Notice of Availability for a Draft Environmental Impact Statement

The general Services Administration (GSA) hereby gives notice a Draft Environmental Impact Statement (DEIS) has been prepared in accordance with the National Environmental Policy Act (NEPA) of 1969, as amended. The DEIS was prepared for the proposed expansion of the Port of Entry located at Pacific Highway, Blaine, Whatcom County, Washington. The DEIS is being made available March 31, 1995. GSA is the lead Federal agency for the preparation of the EIS. The DEIS evaluates the proposed action, the no-action, and three (3) design alternatives.

Written comments should be as specific as possible and may address the adequacy of the EIS, the merits of the alternatives discussed, the impacts identified, and/or mitigation measures recommended and be sent no later than May 15, 1995 to GSA's EIS subconsultant, Berger/ABAM, at the following address: 33301 Ninth Avenue South, Federal Way, WA 98003.

Comments will also be accepted at a public meeting to be held on April 19, 1995, at the Blaine Senior Center, 763 "G" Street, Blaine, Washington 98230. The meeting will be held from 5:30 p.m. to 7:30 p.m.

Representatives of GSA and Berger/ABAM will receive comments from

interested parties regarding the proposed project, the environmental analysis, and proposed mitigation measures. All comments received will be made a part of the administrative record for the DEIS and will be evaluated as part of the Final EIS review process.

For further information contact Donna M. Meyer, Regional Environmental Program Officer, General Services Administration, Public Buildings Service (10PL), 400 15th Street SW., Auburn, Washington 98001-6599, or at (206) 931-7675.

Dated: March 24, 1995.

L. Jay Pearson,

Regional Administrator (10A).

[FR Doc. 95-8414 Filed 4-5-95; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 14 $\frac{1}{8}$ percent for the quarter ended March 31, 1995. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: March 30, 1995.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 95-8397 Filed 4-5-95; 8:45 am]

BILLING CODE 4150-04-M

Food and Drug Administration

[Docket No. 95N-0082]

Animal Drug Export; Deslorelin Acetate Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Peptide Technology Ltd. has filed an application requesting approval for the export of the animal drug Ovuplant™ (deslorelin acetate) to Canada.

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 animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT:

Gregory S. Gates, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1617.

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 Peptide Technology Ltd., 4-10 Inman Rd., Dee Why 2099, Australia, has filed application number 8019 requesting approval for the export of the animal drug Ovuplant™ (2.1 milligrams of deslorelin per implant, as the acetate) to Canada. The drug is a subcutaneous implant providing sustained release of a gonadotropin releasing hormone analog. It is indicated for inducing ovulation in the oestrus mare. The application was received and filed in the Center for Veterinary Medicine on March 20, 1995,

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 April 17, 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 Veterinary Medicine (21 CFR 5.44).

Dated: March 24, 1995.

Robert C. Livingston,
*Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*
[FR Doc. 95-8451 Filed 4-5-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95D-0052]

Changes To Be Reported for Product and Establishment License Applications; Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a guidance document entitled "Changes to be Reported for Product and Establishment License Applications; Guidance." The guidance document is intended to provide manufacturers of licensed biological products guidance on changes in manufacturing procedures and establishments which may be implemented with and without prior approval by the Director, Center for Biologics Evaluation and Research (CBER). This document does not apply to manufacturers of Whole Blood, blood components, Source Leukocytes, and Source Plasma, and it does not address labeling changes. By following this guidance document, manufacturers of licensed biologicals may, in some instances, reduce their reporting burden and facilitate implementation of certain changes.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted except that individuals may submit one copy. A copy of the guidance document and received comments are available in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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

SUPPLEMENTARY INFORMATION: Under § 601.12 *Changes to be reported* (21 CFR 601.12), manufacturers are required to report important proposed changes in location, equipment, management and responsible personnel, or in manufacturing methods and labeling, of any product for which a license is in effect or for which an application for license is pending, to the Director, CBER. Such reports are to be filed by the manufacturer not less than 30 days in advance of the time that such changes are intended to be made except in case of an emergency. Proposed changes in manufacturing methods and labeling may not become effective until notification of acceptance is received from the Director, CBER.

Reporting changes under § 601.12 represents a significant workload for the industry and the agency. In addition, regulated industry has expressed concern about delays in implementing changes and inconsistencies in reporting requirements for product license applications (PLA's), establishment license applications (ELA's), and new drug applications (NDA's). To reduce the reporting burden on manufacturers of biological products and to facilitate the approval process, FDA is issuing this guidance document, which describes CBER's current interpretation of § 601.12(a) and (b).

The guidance document is not intended to affect the reporting requirements currently specified in § 601.12, but to provide clarifying descriptions of the types of changes that are currently considered to be "important" within the meaning of that section. In addition, the document clarifies the types of changes which may be implemented 30 days after

submission of a supplement and those which must await approval of a supplement prior to implementation. Thus, the guidance document outlines three categories for reporting changes, based on the importance and nature of the changes. The document lists examples of changes that would fall into each category.

This document does not apply to changes in manufacturing processes and facilities associated with the manufacture of Whole Blood, blood components, Source Leukocytes, or Source Plasma. CBER is currently evaluating reporting requirements in those areas. In addition, the guidance document does not address labeling changes. However, in the **Federal Register** of August 3, 1994 (59 FR 39570), FDA published a notice of availability for the revised Office of Establishment Licensing and Product Surveillance Advertising and Promotional Labeling Staff (APLS) Procedural Guidance Document. The APLS Procedural Guidance document details the approach that manufacturers and distributors should follow in submitting advertising and promotional material for review by CBER. The APLS Procedural Guidance Document also provides guidance on CBER's current interpretation of § 601.12 as it applies to reporting important proposed changes in labeling; specifically, promotional labeling of biological products for which a license is in effect or for which an application for a license is pending.

As with other guidance documents, FDA does not intend this document to be all inclusive. The document is intended to provide information and does not set forth requirements. Manufacturers may follow the guidance or may choose to use alternative procedures even though they are not provided in this document. If a manufacturer chooses to use alternative procedures, that manufacturer may wish to discuss the matter further with CBER to prevent expenditure of resources on activities that FDA may later determine to be unacceptable.

This guidance document is not binding on either FDA or licensed manufacturers of biological products and does not create or confer any rights, privileges, or benefits for or on any person.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance document. Received comments will be considered to determine if further revision to the guidance document is necessary.

The text of the guidance document follows: