(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 Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64190, has filed application number 4557 requesting approval for the export of the animal drug Denagard® (tiamulin 10 percent) injection for swine to Canada. The product is intended for intramuscular use in swine for the treatment of swine dysentery associated with *Treponema hyodysenteriae*. The application was received and filed in the Center for Veterinary Medicine on December 6, 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 January 29, 1996, 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: December 20, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–469 Filed 1–18–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

Design of Experimental Studies of Transmission of Creutzfeldt-Jakob Disease (CJD) by Plasma and Plasma Derivatives; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a public workshop on design of experimental studies to investigate possible transmission of Creutzfeldt-Jakob Disease (CJD) by plasma and plasma derivatives. This scientific workshop, sponsored by FDA and the National Heart, Lung, and Blood Institute, is intended to foster an indepth discussion of the available laboratory methods which would underlie experimental studies on the transmission of CJD and related diseases by plasma and derived products.

DATES: The public workshop will be held on Monday, January 29, 1996, from 8 a.m. to 4:30 p.m. Preregistration is recommended due to limited seating. Registration is requested by January 22, 1996. There is no registration fee.

ADDRESSES: The public workshop will be held at the National Institutes of Health, Bldg. I, Wilson Hall, 9000 Rockville Pike, Bethesda, MD 20892.

FOR FURTHER INFORMATION CONTACT:

Regarding information on registration: Joseph Wilczek, Center for Biologics Research and Evaluation (HFM–350), FDA, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–6700, or FAX 301–594–6764.

Regarding other information: Joseph C. Fratantoni, Center for Biologics Research and Evaluation (HFM–330), FDA, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–496–4396, or FAX 301–402–2780.

SUPPLEMENTARY INFORMATION: The purpose of this workshop is to provide an opportunity to discuss the elements required to initiate and execute meaningful experiments that will further our understanding of the risk of potential transmission of CJD and related disorders by blood, plasma, and derived products. The workshop will foster detailed discussion of available techniques among investigators, manufacturers, and regulators.

Topics to be presented include the following: (1) Detection systems available for use in studies of CJD; (2) animal models and the biology of CJD and related disorders; (3) experimental design for testing the infectivity of plasma derivatives; and (4) inactivation and partitioning of the infectious agent in the manufacturing process for plasma derivatives.

FDA will consider information presented and discussed at the workshop in identifying topics for future discussion.

Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page.

Dated: January 16, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–638 Filed 1–17–96; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

[BPD–854–NC]

Medicare and Medicaid Programs; Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Area

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: In accordance with the Social Security Amendments of 1994, this notice announces applications received from hospitals requesting waivers from dealing with their designated area organ procurement organizations (OPOs). Effective January 1, 1996, a hospital is required to have an agreement with the OPO designated for the area in which it is located unless granted a waiver to have an agreement with an alternative OPO. This notice requests comments from OPOs and the general public for consideration by us in determining whether such a waiver should be granted.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 19, 1996.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–854–NC, P.O. Box 7517, Baltimore, MD 21244–0517.