(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.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–854–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1138 of the Social Security Act (the Act) provides that a hospital or rural primary care hospital that participates in the Medicare or Medicaid programs must establish written protocols for the identification of potential organ donors. Section 155 of the Social Security Amendments of 1994 (SSA '94) (Public Law 103–432) amended section 1138 of the Act to require that effective January 1, 1996, a hospital may have an agreement concerning organ procurement only with its designated Organ Procurement Organization (OPO) unless it obtains a waiver from the Secretary that would allow the hospital to have an agreement with a different OPO. This section also provides that any hospital that had an agreement with an out-of-area OPO on the date of enactment, October 31, 1994, must submit a waiver request to the Secretary by January 1, 1996, if it wishes to retain the agreement. The existing agreement would remain in effect pending the Secretary's determination.

The law further states that in granting a waiver for an out-of-area agreement, the Secretary must determine that such a waiver: (1) Would be expected to increase donation; and (2) will assure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the out-of-area OPO. In making a waiver determination, the Secretary may consider, among other factors: (1) cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO service area due to definition of metropolitan statistical areas (MSA); and (4) the length and continuity of a hospital's relationship with the out-of-area OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver applications within 30 days of receiving the application and offer interested parties an opportunity to comment in writing within 60 days of the published notice.

II. Hospital Requests for Waiver

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) that has been supplied to each hospital. This Program Memorandum detailed the waiver process and discussed the information that may be provided by hospitals requesting a waiver. As required by law, we indicated that upon receipt of the waiver requests, we would publish a notice to solicit comments.

Upon receipt of the comments, we will review the request and comments received. During the review process, we may consult on an as needed basis with parties other than those that submitted comments including the Public Health Service's Division of Transplantation, the United Network for Organ Sharing, and HCFA regional offices. If necessary, we may also request additional clarifying information from the applying hospital. It should be noted that there is no time limit upon which we must complete our review. We then will make a determination on the waiver requests and notify the affected hospitals and OPOs.

III. Hospitals Requesting Waivers

To date, we have received waiver applications from the following hospitals:

Hospital Name: West Florida Regional Medical Center
City & State: Pensacola, FL
Requested OPO: Alabama Organ Center
City & State: Birmingham, AL
Designated OPO: University of Florida
City & State: Gainesville, FL

Hospital Name: Singing River Hospital System
City & State: Pascagoula, MS
Requested OPO: Alabama Organ Center
City & State: Birmingham, AL
Designated OPO: Mississippi Organ Recovery Agency
City & State: Jackson, MS

Hospital Name: Jefferson Memorial Hospital
City & State: Ranson, WV
Requested OPO: Virginia's Organ Procurement Agency
City & State: Midlothian, VA
Designated OPO: Center Organ Recovery & Education
City & State: Pittsburgh, PA

Hospital Name: City Hospital
City & State: Martinsburg, WV
Requested OPO: Virginia's Organ Procurement Agency
City & State: Midlothian, VA
Designated OPO: Center Organ Recovery & Education
City & State: Pittsburgh, PA

Hospital Name: Princeton Community Hospital
City & State: Princeton, WV
Requested OPO: Virginia's Organ Procurement Agency
City & State: Midlothian, VA
Designated OPO: Center Organ Recovery & Education
City & State: Pittsburgh, PA

Hospital Name: Fort Walton Beach Medical Center
City & State: Ft. Walton Beach, FL
Requested OPO: Alabama Organ Center
City & State: Birmingham, AL
Designated OPO: University of Florida
City & State: Gainesville, FL

Hospital Name: Baylor Medical Center at Grapevine
City & State: Grapevine, TX
Requested OPO: Southwest Organ Bank
City & State: Dallas, TX
Designated OPO: Life Gift Organ Donation Center
City & State: Houston, TX

Hospital Name: St. Joseph Regional Health Center
City & State: Bryan, TX
Requested OPO: Southwest Organ Bank
City & State: Dallas, TX
Designated OPO: Life Gift Organ Donation Center
City & State: Houston, TX

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b–8).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 30, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 96–644 Filed 1–17–96; 8:45 am]

BILLING CODE 4120–01–P