Office of Protection from Research Risks at the National Institutes of Health.

Women and Minority Inclusion Policy

It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951.

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Specialist (whose address is reflected in section B, ''Applications''). It should be postmarked no later than one month prior to the planned submission deadline, (e.g., February 14 for March 14 submission). The letter should identify the announcement number, name the principal investigator, and specify the priority area of violence-related injury research (i.e., suicidal behavior, assaultive behavior among youth, and family and intimate violence) addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Applications

Applicants should use Form PHS–398 (OMB No. 0925–0001 Revised 5/95) and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies, on or before March 14, 1996, to: Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305.

C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

A. Received at the above address on or before the deadline date, or

B. Sent on or before the deadline date to the above address, and received in time for the review process. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailings.

2. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 611. You will receive a complete program description, information on application procedures, and application forms. The announcement is also available through the CDC homepage on the Internet. The address for the CDC home page is [http://www.cdc.gov]. CDC will not send application kits by facsimile or express mail.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Lisa Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6796.

Programmatic technical assistance may be obtained from Ted Jones, Project Officer, Extramural Research Grants Branch, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), Mailstop K–58, 4770 Buford Highway, NE., Atlanta, GA 30341–3724, telephone (404) 488–4824.

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) 512–1800.

Copies of ''Injury Control in the 1990s: A National Plan for Action,'' (Atlanta: Centers for Disease Control and Prevention, 1993) and ''A Framework for Assessing the Effectiveness of Disease and Injury Prevention,'' (CDC, ''Morbidity and Mortality Weekly Report,'' March 27, 1992, Volume 41, Number RR–3, pages 5–11) may be obtained by calling (404) 488–4265.

Information for obtaining the suggested readings, ''Violence and the Public's Health,'' ''Understanding and Preventing Violence,'' and ''Violence in America: A Public Health Approach,'' is included on a separate sheet with the application kit.

Dated: January 11, 1996.

Joseph R. Carter,

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

[FR Doc. 96–566 Filed 1–18–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 95N–0407]

Animal Drug Export; Denagard® (Tiamulin) Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Fermenta Animal Health Co. has filed an application requesting approval for the export of the animal drug Denagard® (tiamulin) injection for swine to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of food animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

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 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.