application. To meet this requirement, the agency is providing notice that Deprenyl Animal Health, Inc., 10955 Lowell, suite 710, Overland Park, KS 66210, has filed application number 8008 requesting approval for export of the animal drug ANIPRYL® (l-selegeline hydrochloride, l-deprenyl hydrochloride) tablets to Canada. The drug is administered orally for the treatment of uncomplicated canine pituitary dependent hyperadrenocorticism. The tablets are not indicated for treatment of other forms of Cushing's syndrome. The application was received and filed in the Center for Veterinary Medicine on January 4, 1996, 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 February 5, 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: January 18, 1996.

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

FOR FURTHER INFORMATION, CONTACT: Bonnie Edington (410) 786-6617.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2355 of the Deficit Reduction Act of 1984 (Pub. L. 98-369) required the Secretary to grant demonstration waivers for social health maintenance organization (SHMO) projects that provide for the integration of health and social services at a fixed annual prepaid capitation rate.

Section 4207(b)(4)(B) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) amended section 2355 of Pub. L. 98-369 to include a requirement that the Secretary conduct up to four additional SHMO projects to demonstrate the effectiveness and feasibility of innovative approaches to refining current targeting and financing methodologies and benefit design for SHMOs.

Section 13567(b) of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66) further amended section 2355 of Pub. L. 98-369, requiring the Secretary to include the integration of acute and chronic care management for patients with end-stage renal disease through expanded community care case management services in at least one of the four additional SHMO projects.

II. Provisions of this Notice

This notice is to inform interested parties of the opportunity to apply for funds for a cooperative agreement from HCFA’s Office of Research and Demonstrations for the “End-Stage Renal Disease (ESRD) Managed Care Demonstration.”

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