

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-selegiline 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 of Veterinary Medicine.
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Health Care Financing Administration [ORD-078-N]

Medicare Program; Announcement of Funding Availability for a Cooperative Agreement for an End-Stage Renal Disease (ESRD) Managed Care Demonstration

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

ACTION: Notice.

SUMMARY: This notice is to inform interested parties of an 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."

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 (OBRA) 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 to operate an "End-Stage Renal Disease (ESRD) Managed Care Demonstration," involving the treatment of Medicare-eligible ESRD patients in a managed care setting as required by OBRA 1993. Interested parties are required to submit an official application for consideration for grant funding and commencement of site development activities. Subject to funds availability, a one-time award of approximately \$175,000 is expected to be given to each selected awardee. HCFA expects to award one or more demonstrations through the application process.

Any organizational entity may apply. However, the applicant must be capable of assuring that the service delivery system under the demonstration will integrate acute and chronic care services, through expanded community care case management services, for ESRD patients. In addition, the

applicant must meet all applicable State requirements for bearing financial risk.

Awardees are expected to have a 9 to 12-month development period subsequent to award and prior to service delivery. In the three-year service delivery phase of the demonstration, awardees will be paid on a capitation basis in which the capitation amount will be adjusted to reflect treatment status (that is, maintenance dialysis, transplant, or functioning graft).

Potential applicants who wish to request the full solicitation and application packet should call Ms. Edington at the above telephone number, send an E-mail message to BEDINGTON@HCFA.GOV, or write to the following address: Bonnie Edington, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3-24-07, 7500 Security Boulevard, Baltimore, MD 21244-1850. These packets will be mailed to all requestors within approximately 10 days from the date of this notice.

Completed applications, including full proposals, will be due approximately 70 days following the date of this notice. The exact due date for applications will be specified in the application packet. Awards are expected to be made in 1996.

Authority: Section 402 of the Social Security Amendments of 1967, as amended (42 U.S.C. 1395b-1); section 222(a) of the Social Security Amendments of 1972, as amended (42 U.S.C. 1395-1(note)); section 2355 of the Deficit Reduction Act of 1984, as amended; section 4207(b)(4)(B) of the Omnibus Budget Reconciliation Act of 1990; section 13567(b) of the Omnibus Budget Reconciliation Act of 1993.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.779 Health Financing Research, Demonstrations and Experiments)

Dated: October 3, 1995.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

[FR Doc. 96-1261 Filed 1-25-96; 8:45 am]

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[BPO-134-NC]

Medicare Program; Revised Criteria and Standards for Evaluating Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Regional Carriers' Performance Beginning February 1, 1996

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