

DMB

Publication Date	1/12
Publication Date	1/13
Certifier	C. Harris

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Selegiline Hydrochloride Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for oral veterinary prescription use of selegiline hydrochloride tablets for dogs for the control of clinical signs associated with cognitive dysfunction syndrome.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 141-080 that provides for oral veterinary prescription use of Anipryl® (selegiline hydrochloride) tablets for dogs for the control of clinical signs associated with canine cognitive dysfunction syndrome. The product is approved for the control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism. The supplement is approved as of December 10, 1998, and the regulations are amended by revising 21 CFR 520.2098 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, except on Federal holidays.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning December 10, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved or any studies of animal safety required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to veterinary prescription use of the drug in dogs for the control of clinical signs associated with cognitive dysfunction syndrome.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.2098 is amended by redesignating paragraphs (d)(2) and (d)(3) as paragraphs (d)(1)(i) and (d)(1)(ii), respectively, and by adding paragraph (d)(2) to read as follows:

§ 520.2098 **Selegiline hydrochloride tablets.**

* * * * *

(d) *Conditions of use.* * * *

(2) *Dosage*. 0.5 to 1.0 milligram per kilogram of body weight once daily.

(i) *Indications for use*. For the control of clinical signs associated with canine cognitive dysfunction syndrome.

;

(ii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 1/6/98

:

S F S / K

Stephen F. Sundlof
Director
Center for Veterinary
Medicine

[FR Doc. 98-???, Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Carolyn C. Harris