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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clomipramine Hydrochloride Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for oral veterinary prescription use of clomipramine hydrochloride tablets to be used as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

**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, 301-827-7540.

**SUPPLEMENTARY INFORMATION:** Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419-8300, filed NADA 141-120 that provides for oral veterinary prescription administration of Clomicalm™ (clomipramine hydrochloride) tablets at 2 to 4 milligrams (mg)/kilogram body weight per day (0.9 to 1.8 mg per pound per day) administered as a single daily dose or divided twice daily to dogs greater than 6 months of age. The NADA is approved as of December 10, 1998, and the regulations are amended in 21 CFR part 520 by adding new § 520.455 to reflect the approval. The basis for 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 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for a 5-year period of marketing exclusivity beginning December 10, 1998, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

FDA 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 520.455 is added to read as follows:

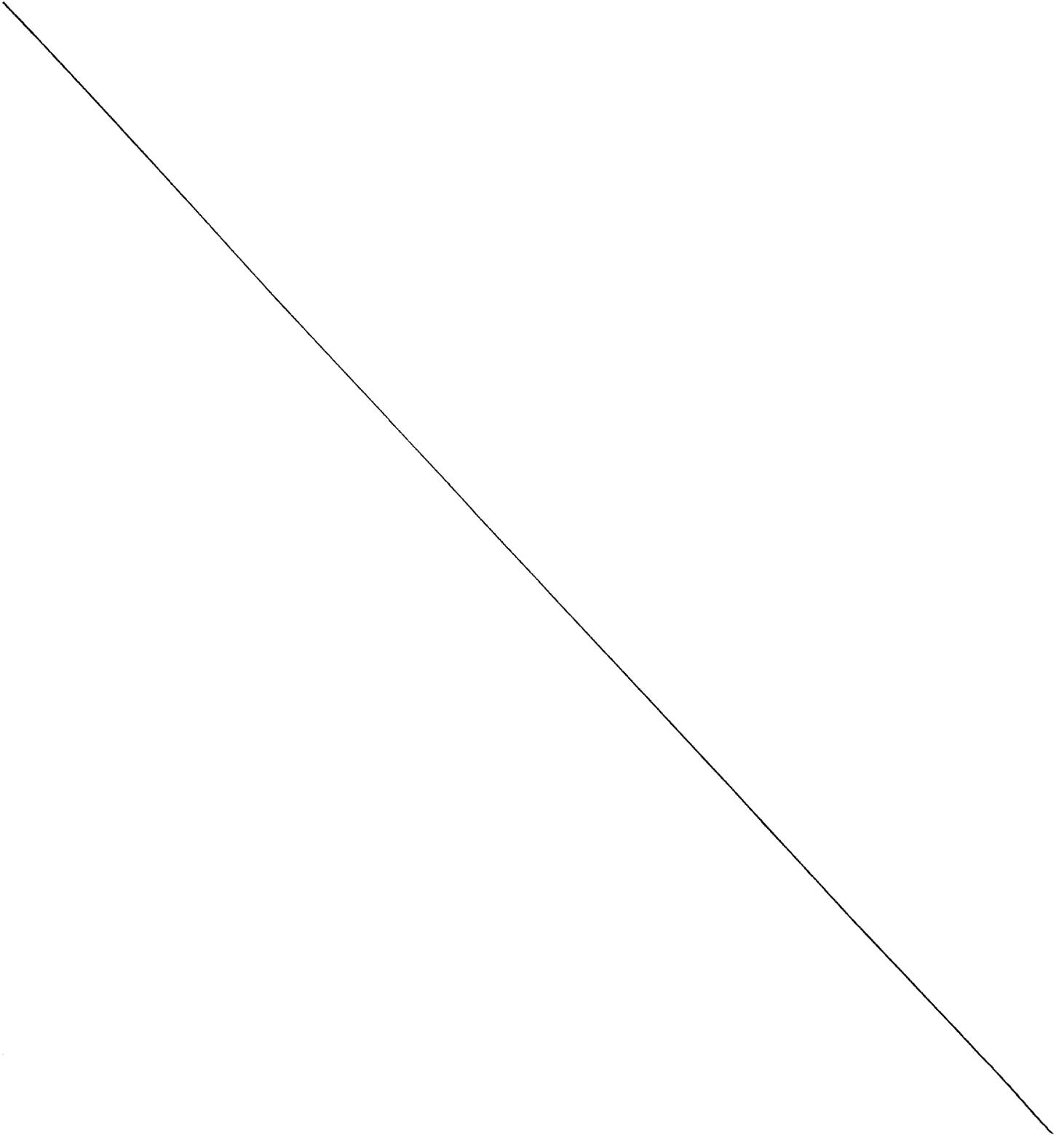
#### **§ 520.455 Clomipramine hydrochloride tablets.**

(a) *Specifications.* Each tablet contains 20, 40, or 80 milligrams of clomipramine hydrochloride.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use*. For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.



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

Dated: 1/4/99

January 4, 1999

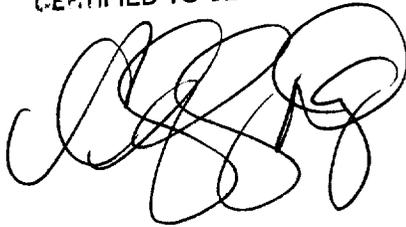
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Stephen F. Sundlof  
Director  
Center for Veterinary Medicine

HL [FR Doc. 98-<sup>9</sup>???? Filed ??-??-98<sup>9</sup>; 8:45 am]

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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