

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Suspension

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 new animal drug application (NADA) filed by Ciba Animal Health, Ciba-Geigy Corp. The NADA provides for oral administration of lufenuron suspension to cats for the control of flea populations.

EFFECTIVE DATE: April 26, 1995.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0614.

SUPPLEMENTARY INFORMATION: Ciba Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, filed NADA 141-026, which provides for oral administration of Program® (Lufenuron) Suspension to cats 6 weeks of age or older. The drug is provided once a month, mixed in food, for the control of flea populations. The product contains six individual dose packs of 135 or 270 milligrams lufenuron. Lufenuron has no deleterious effect on adult fleas, but it prevents most flea eggs from hatching or maturing into adults. The NADA is approved as of March 28, 1995, and the regulations are amended in part 520 (21 CFR 520) by adding new § 520.1289 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning March 28, 1995, because it contains reports of

new clinical or field investigations, other than bioequivalence or residue studies, essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.1289 is added to read as follows:

§ 520.1289 Lufenuron suspension.

(a) *Specifications.* Each individual dose pack contains either 135 or 270 milligrams of lufenuron.

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

(c) *Conditions of use in cats—(1) Amount.* Minimum of 13.6 milligrams per pound of body weight (30 milligrams per kilogram). Recommended dose of 135 milligrams for up to 10 pounds of body weight or 270 milligrams for 11 to 20 pounds. Cats over 20 pounds are provided the appropriate combination of packs.

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, mixed with food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no effect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 19, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 6, 8, 10 and 11

[T.D. ATF-364, Re: Notice No. 794 and Notice No. 796]

RIN 1512-AB10

Unfair Trade Practices Under the Federal Alcohol Administration Act (93F-003P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is amending trade practice regulations under the Federal Alcohol Administration (FAA) Act on tied-house, exclusive outlets, commercial bribery, and consignment sales by adding standards for enforcing the "exclusion" element where appropriate. Under the FAA Act, "exclusion, in whole or in part, of distilled spirits, wine, or malt beverages, sold or offered for sale by other persons" is a necessary element of a violation of the tied-house, exclusive outlets or commercial bribery provisions. In this final rule, ATF promulgates a framework for establishing "exclusion," identifies promotional practices which result in control of a retailer or in exclusion under the Act, identifies factors which will apply in evaluating exclusion, and identifies those practices for which there is no likelihood that exclusion will result and for which the Bureau will not take action (safe harbors). Other regulatory amendments are also made as a result of an ATF review of the regulations and an industry petition submitted in 1992.

EFFECTIVE DATE: May 26, 1995.

FOR FURTHER INFORMATION CONTACT: James R. Crandall, Coordinator, Market Compliance Branch, 650 Massachusetts Avenue, NW, Washington, DC 20226; telephone (202) 927-8100.

SUPPLEMENTARY INFORMATION:**Background**

The Federal Alcohol Administration Act

The Federal Alcohol Administration Act (hereinafter referred to as FAA Act