

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The general authority citation for part 4 and the specific authority citation for § 4.22 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 46 U.S.C. App. 3, 91.

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Section 4.22 also issued under 46 U.S.C. App. 121, 128, 141;

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§ 4.22 [Amended]

2. Section 4.22 is amended by removing "Brazil" from the list of nations entitled to exemption from special tonnage taxes and light money.

Dated: September 29, 1998.

Harold M. Singer,

Chief, Regulations Branch

[FR Doc. 98-26417 Filed 10-1-98; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 520****Oral Dosage Form New Animal Drugs; Lufenuron 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 Novartis Animal Health US, Inc. The supplemental NADA provides for revising the specifications and conditions of use of lufenuron tablets for dogs and cats for control of flea populations.

EFFECTIVE DATE: October 2, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 26402, Greensboro, NC 27404-6402, filed supplemental NADA 141-035 that provides for revising the specifications and conditions of use of Program™ (lufenuron) tablets for prevention and control of flea populations in dogs and control of flea populations in cats. The supplemental NADA is approved as of August 1, 1998, and the regulations are amended by revising 21 CFR 520.1288

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 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.

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 520.1288 is revised to read as follows:

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) *Dogs*. Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) of lufenuron.

(2) *Cats*. Each tablet contains either 90, 135, 204.9 or 270 mg of lufenuron.

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

(c) *Conditions of use in dogs*—(1) *Amount*. Minimum of 10 mg of lufenuron per kilogram (4.5 mg per pound (lb)) of body weight.

(2) *Indications for use*. For use in dogs and puppies, 6 weeks of age and older, for the prevention and control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations*. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

(d) *Conditions of use in cats*—(1) *Amount*. Minimum of 30 mg of lufenuron per kilogram (13.6 mg/lb) of body weight.

(2) *Indications for use*. For use in cats and kittens, 6 weeks of age and older, for the control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(3) *Limitations*. Administer tablet(s) after or in conjunction with a full meal to ensure adequate absorption. Administer tablet(s) once a month. All dogs and cats in a household should be treated to achieve maximum efficacy.

Dated: September 20, 1998.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98-26423 Filed 10-1-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 558****New Animal Drugs For Use In Animal Feeds; Tiamulin and Chlortetracycline**

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 Boehringer Ingelheim Vetmedica, Inc. The supplemental NADA provides for an additional source of chlortetracycline (CTC) Type A medicated articles used to make Type B and C medicated swine feeds containing tiamulin and CTC.

EFFECTIVE DATE: October 2, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc. (BIV), 2621 North Belt Hwy., St. Joseph, MO 64506-2002, has filed supplemental NADA 141-011 that provides for using an additional source of CTC Type A medicated articles (Pennfield Oil Co.'s Pennchlor®) for the feed-mixed combination use with tiamulin Type A medicated articles (BIV's Denagard®) to make tiamulin/CTC Type B or C medicated swine feeds for use as