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.

* * * * *

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

* * * * *

§ 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

described in § 558.600(c)(4) (21 CFR 558.600(c)(4)). The supplemental NADA is approved as of August 6, 1998, and the regulations are amended in § 558.600(c)(4)(ii) to reflect the approval.

Approval of this supplemental NADA does not require additional safety or effectiveness data. A freedom of information summary as provided under 21 CFR part 20 and 514.11(e)(2)(ii) is not required.

The agency has determined under 21 CFR 25.33(a)(3) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.600 [Amended]

2. Section 558.600 *Tiamulin* is amended in paragraph (c)(4)(ii) by removing ''046573 and 063238'' and adding in its place ''046573, 053389, and 063238''.

Dated: September 20, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–26426 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; Monensin and Bacitracin Methylene Disalicylate

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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for using approved single ingredient monensin and bacitracin methylene disalicylate (BMD) Type A medicated articles to make an additional approved combination for a monensin/BMD Type C medicated turkey feed.

EFFECTIVE DATE: October 2, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 140–937 that provides for combining approved Coban® (45 and 60 grams per pound (g/lb) monensin) and BMD® (25, 30, 40, 50, 60, or 75 g/lb BMD) Type A medicated articles to make Type C medicated turkey feeds containing 54 to 90 g/ton (t) monensin and 200 g/t BMD. The monensin/BMD Type C turkey feeds are used for the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagrimitis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to BMD. The supplemental NADA is approved as of August 13, 1998, and 21 CFR 558.355(f)(2)(iii) is added 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.

The agency has determined under 21 CFR 25.33(a)(2) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1.The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraph (f)(2)(iii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(iii) *Amount per ton*. Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 200 grams.

(*a*) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagrimitis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(*b*) *Limitations*. For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

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Dated: September 20, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–26425 Filed 10–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2894]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended—Fees for Application and Issuance of Nonimmigrant VIsas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule finalizes, with one amendment, the interim rule published May 1, 1998, (63 FR 24107) relating to the waiver of visa fees for a