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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Praziquantel, Pyrantel Pamoate, and Febantel 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 Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for use of a larger size of praziquantel/pyrantel pamoate/febantel tablet for the removal of several species of internal parasites in dogs.

DATES: This rule is effective April 28, 2003.

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, e-mail: *mberson@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141–007 that provides for use of a larger size of DRONTAL PLUS (praziquantel/pyrantel pamoate/febantel) Tablets for the removal of several species of internal parasites in dogs. The supplemental NADA is approved as of February 10, 2003, and the regulations are amended in 21 CFR 520.1872 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 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, 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 520.1872 is amended by adding new paragraph (a)(3), and by revising the table in paragraph (c)(1)(i) to read as follows:

§ 520.1872 Praziquantel, pyrantel pamoate, and febantel tablets.

(a) * * *

(3) Tablet No. 3: 136 milligrams (mg) praziquantel, 136 mg pyrantel base, and 680.4 mg febantel.

* * * * *

(c) * * *

(1) * * *

(i) * * *

Weight of animal		Number of tablets per dose		
Kilograms	Pounds	Tablet no. 1	Tablet no. 2	Tablet no. 3
0.9 to 1.8	2 to 4	1/2		
2.3 to 3.2	5 to 7	1		
3.6 to 5.4	8 to 12	1 1/2		
5.9 to 8.2	13 to 18	2		
8.6 to 11.4	19 to 25	2 1/2		
11.8 to 13.6	26 to 30		1	
14.1 to 20.0	31 to 44		1 1/2	
20.4 to 27.2	45 to 60		2	1
27.7 to 40.9	61 to 90			1 1/2
41.3 to 54.5	91 to 120			2

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Dated: April 4, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–10416 Filed 4–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline and Sulfamethazine

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 an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides for the use of a fixed-combination Type A medicated article containing chlortetracycline and sulfamethazine to make two-way combination drug Type C medicated feeds for beef cattle.

DATES: This rule is effective April 28, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed ANADA 200–314 for use of PENNCHLOR S 700 (chlortetracycline/sulfamethazine), a fixed-combination Type A medicated article used to make two-way combination drug Type C medicated feeds for beef cattle. Pennfield Oil Co.'s PENNCHLOR S 700 Type A medicated article is approved as a generic copy of Alpharma Inc.'s AUREO S 700, approved under NADA 35–805. The ANADA is approved as of January 29, 2003, and the regulations are amended in 21 CFR 558.140 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 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, 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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.

§ 558.140 [Amended]

■ 2. Section 558.140 *Chlortetracycline and sulfamethazine* is amended in paragraph (a) by removing ''046573'' and by adding in its place ''Nos. 046573 and 053389''.

Dated: April 1, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–10418 Filed 4–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–03–048]

RIN 1625–AA09

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, Miles 1062.6 and 1064.0 at Fort Lauderdale, Broward County, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations governing the operation of the East Sunrise Boulevard (SR 838) and East Las Olas bridges, miles 1062.6 and 1064.0, in Fort Lauderdale, Florida. This temporary rule allows these bridges to not open for periods of time on May 3 and 4, 2003, to facilitate the vehicle traffic flow to and from the Air & Sea Show, while still providing for the reasonable needs of navigation.

DATES: This rule is effective from 4 p.m. on May 3 to 6 p.m. on May 4, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of this docket and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, FL 33131 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch at (305) 415–6744.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NRPM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM for this regulation. Publishing an NPRM was impracticable and contrary to the public interest. There was insufficient time remaining to publish an NPRM after we received this request to change the bridges' operating schedules, and further delaying the event to follow normal rulemaking procedures before incorporating this important safety measure would have a significant negative effect on the outcome of this highly-attended event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. We did not receive this request to change the bridges' operating schedules with sufficient time remaining to delay the rule's effectiveness until 30 days after its publication. Further, delaying the event to follow normal rulemaking procedures before incorporating this important safety measure would have a significant negative effect on the outcome of this highly-attended event.

Background and Purpose

The East Las Olas Boulevard bridge, mile 1064.0, has a vertical clearance of 31 feet above mean high water and a horizontal clearance of 91 feet between