PART 388—INFORMATION AND REQUESTS

1. The authority citation for part 388 continues to read as follows:

Authority: 5 U.S.C. 301–305, 551, 552 (as amended), 553–557; 42 U.S.C. 7101–7352.

2. In § 388.109, paragraph (a)(4)(i) is revised to read as follows:

* * * * *

§ 388.109 Fees for record requests.

(a) * * *

(4)(i) The public may purchase hard copies of documents available in electronic form from the Commission's Federal Energy Regulatory Records Information System (FERRIS) for 20 cents per page.

[FR Doc. 02–10808 Filed 5–1–02; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved abbreviated new animal drug applications (ANADAs) from Blue Ridge Pharmaceuticals, Inc., to Virbac AH, Inc.

DATES: This rule is effective May 2, 2002.

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, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249–105 Piedmont Pkwy., Greensboro, NC 27410, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 200–270 for IVERHART (ivermectin) Tablets, NADA 200–281 for WORMEXX (pyrantel pamoate) Chewable Tablets, and NADA 200–302 for IVERHART Plus (ivermectin/pyrantel pamoate) Flavored Chewable Tablets to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137. Accordingly, the agency is amending the regulations in 21 CFR 520.1193, 520.1196, and 520.2041 to reflect the transfer of ownership.

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.

§ 520.1193 [Amended]

2. Section 520.1193 *Ivermectin tablets and chewables* is amended in paragraph (b)(2) by removing ''065274'' and by adding in its place ''051311''.

§ 520.1196 [Amended]

3. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in the section heading by removing ''tablet'' and by adding in its place ''tablets''; and in paragraph (b) by removing ''065274'' and by adding in its place ''051311''.

§ 520.2041 [Amended]

4. Section 520.2041 *Pyrantel pamoate chewable tablets* is amended in paragraph (b) by removing ''065274'' and by adding in its place ''051311''.

Dated: April 3, 2002..

Andrew J. Beaulieu,

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

[FR Doc. 02–10793 Filed 5–1–02; 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; Tilmicosin

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. The supplemental NADA provides for additions to labeling of tilmicosin for use in swine feed.

DATES: This rule is effective May 2, 2002.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–064 that provides for the use of PULMOTIL (tilmicosin phosphate) Type A medicated article in swine feed for the control of swine respiratory disease associated with certain bacterial organisms. The supplemental NADA provides for additional use information in labeling. The supplemental NADA is approved as of November 15, 2001, and the regulations are amended in 21 CFR 558.618 to reflect the approval.

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)(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 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 558.618 is amended by redesignating paragraphs (a) through (d) as paragraphs (b) through (e), respectively; by adding new paragraph (a); and by revising newly redesignated paragraphs (b), (c), and (e)(3) to read as follows:

§ 558.618 Tilmicosin.

(a) *Specifications.* Type A medicated article containing 20 percent tilmicosin as tilmicosin phosphate (90.7 grams per pound).

(b) *Approvals. See* No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law limits this drug to use under the professional supervision of a licensed veterinarian. *See* § 558.6 of this chapter for additional requirements for the use of products regulated as veterinary feed directives (VFDs).

(2) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance. VFDs for tilmicosin shall not be refilled.

(3) Do not use in Type B or Type C medicated feeds containing bentonite.

* * * * *

(e) * * *

(3) *Limitations.* Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an expected disease outbreak. Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial. The safety of tilmicosin has not been established in pregnant swine or swine intended for breeding purposes. Do not allow horses or other equines access to feeds containing tilmicosin. Withdraw 7 days before slaughter.

Dated: April 9, 2002.

Andrew J. Beaulieu,

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

[FR Doc. 02–10792 Filed 5–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–02–050]

RIN 2115–AE47

Drawbridge Operation Regulations: Newtown Creek, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of the Pulaski Bridge, mile 0.6, across Newtown Creek between Brooklyn and Queens, New York. This temporary final rule allows the bridge to remain closed from 9:30 a.m. to 11:30 a.m. on May 5, 2002. This action is necessary for public safety, to facilitate the running of the Five Borough Bike Tour Race.

DATES: This temporary final rule is effective on Sunday, May 5, 2002.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–02–50) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, 6:30 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Schmied, Project Officer, First Coast Guard District, (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard has determined that good cause exists under the Administrative Procedure Act (5 U.S.C. 553) to forego notice and comment for this rulemaking and for making this regulation effective in less than 30 days after publication in the **Federal Register**. Processing and publication of this temporary rule 30 days prior to the effective date was not possible due to the late notification provided to the Coast Guard. The Coast Guard believes notice and comment are not necessary because the requested closure is of short duration on a Sunday when there have been few requests to open this bridge. The Newtown Creek is used mostly by commercial vessels and those vessels normally pass under the draws without openings. The commercial vessels that do require openings are work barges that do not operate on Sundays. The Coast Guard, for the reasons just stated, has also determined that good cause exists for this rule to be effective less than 30 days after it is published in the **Federal Register**.

Background

The Pulaski Bridge, mile 0.6, across the Newtown Creek between Brooklyn and Queens, has a vertical clearance of 39 feet at mean high water and 43 feet at mean low water in the closed position. The existing operating regulations listed at 117.801(g) require the draw to open on signal, if at least a two-hour advance notice is given.

New York City Department of Transportation requested a temporary change to the operating regulations to allow the Pulaski Bridge to remain in the closed position from 9:30 a.m. to 11:30 a.m. on May 5, 2002, for the running of the Five Borough Bike Tour. Vessels that can pass under the bridges without bridge openings may do so at all times.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). This conclusion is based on the fact that the requested closure is of short duration and on Sunday morning when there have been few requests to open the bridge.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rule would have a significant economic impact on a substantial number of small entities. ''Small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that the requested closure is of short duration and on Sunday when there have been few requests to open the bridge.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121),