

powder for skeletal marking of finfish fry and fingerlings by immersion.

DATES: This rule is effective February 11, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (301) 827-7571, e-mail: jgotthar@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 130-435 that provides for use of OXYMARINE (oxytetracycline hydrochloride) Soluble Powder for skeletal marking of finfish fry and fingerlings by immersion. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5667 which were compiled under National Research Support Project 7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. The supplemental NADA is approved as of December 24, 2003, and the regulations are amended in 21 CFR part 529 by adding § 529.1660 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 Division of Dockets Management (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.

FDA has determined under 21 CFR 25.33(d)(4) 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

21 CFR Part 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 529 and 556 are amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. Section 529.1660 is added to read as follows:

§ 529.1660 Oxytetracycline.

(a) *Specifications.* Each gram of powder contains 366 milligrams (mg) of oxytetracycline hydrochloride.

(b) *Sponsor.* See No. 046573 in § 510.600 of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in finfish—(1) Amount.* Immerse fish in a solution containing 200 to 700 mg oxytetracycline hydrochloride (buffered) per liter of water for 2 to 6 hours.

(2) *Indications for use.* For skeletal marking of finfish fry and fingerlings.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.500 [Amended]

■ 4. Section 556.500 *Oxytetracycline* is amended in paragraph (b) by removing "catfish, lobster, and salmonids" and by adding in its place "finfish, and lobster".

Dated: January 30, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 04-2894 Filed 2-10-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 revised labeling for the use of single-ingredient monensin Type A medicated articles to make Type C medicated feeds used for the prevention and control of coccidiosis in feedlot cattle. The regulations are being amended to remove a redundant entry for use of monensin in Type C medicated cattle feeds.

DATES: This rule is effective February 11, 2004.

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

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95-735 for use of RUMENSIN 80 (monensin sodium) Type A medicated article. The supplemental NADA provides revised labeling for Type C medicated feeds containing 10 to 30 grams per ton (g/ton) of monensin used for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in feedlot cattle. This revised labeling replaces labeling approved in 1998 for this indication (64 FR 5158, February 3, 1999). The supplemental application is approved as of December 12, 2003, and the regulations are amended in 21 CFR 558.355(f)(3)(vii) to remove indications for improved feed efficiency in cattle feeds containing 10 to 30 g/ton of monensin. This indication for use is already codified in 21 CFR 558.355(f)(3)(i) for cattle feeds containing 5 to 30 g of monensin per ton.

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 Division of Dockets Management (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 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.

§ 558.355 [Amended]

■ 2. Section 558.355 *Monensin* is amended in paragraph (f)(3)(vii)(a) by removing "improved feed efficiency; for"; and in paragraph (f)(3)(vii)(b) by removing "feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis,".

Dated: January 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–2893 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD13–04–004]

Drawbridge Operation Regulations; Snake River, Burbank, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Burlington Northern Santa Fe Railroad Drawbridge across the Snake River, mile 1.5, at Burbank, Washington. This deviation allows the vertical lift span to be temporarily closed during two periods while wire ropes are replaced.

The deviation is necessary to facilitate this essential maintenance.

DATES: This deviation is effective from 8 a.m. March 8 through 5 p.m. March 12, 2004, and from 8 a.m. March 15 through 5 p.m. March 16, 2004.

ADDRESSES: Materials referred to in this document are available for inspection or copying at Commander (oan), Thirteenth Coast Guard District, 915 Second Avenue, Seattle, Washington 98174–1067 between 7:45 a.m. and 4:15 p.m., Monday through Friday, except Federal holidays. The telephone number is (206) 220–7270. The Bridge Section of the Aids to Navigation and Waterways Management Branch maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT:

Austin Pratt, Chief, Bridge Section, Aids to Navigation and Waterways Management Branch, (206) 220–7282.

SUPPLEMENTARY INFORMATION: The Burlington Northern Santa Fe Railroad (BNSF) requested this deviation from normal operations to facilitate the replacement of wire ropes on the lift span and its supporting towers. This project is occurring during the annual lock maintenance closure on the Snake River. During lock closure commercial traffic will be much reduced so that few, if any, vessels will be hindered by this bridge maintenance project. Currently, this drawbridge is maintained in the open position except for the passage of trains.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: February 3, 2004.

Jeffrey M. Garrett,

Rear Admiral, U. S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 04–2989 Filed 2–10–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–04–019]

Drawbridge Operation Regulations; Loxahatchee River, Palm Beach County, FL

AGENCY: U.S. Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Florida East Coast Railway bridge across the Loxahatchee River, mile 1.2, Jupiter, Florida. This deviation allows the bridge to remain in the closed position from 8 a.m. to 12:30 p.m. and 1 p.m. to 5 p.m. Monday through Friday from February 10 until March 12, 2004, for repairs.

DATES: This deviation is effective from 8 a.m. on February 10 until 5 p.m. on March 12, 2004.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket [CGD07–04–019] will become part of this docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Miami, Florida 33131–3050 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: The Florida East Coast Railway bridge across the Loxahatchee River, Jupiter, Florida, is a single leaf bascule bridge with a vertical clearance of 4 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 40 feet. The current operating regulation in 33 CFR 117.300 requires that: (a) The bridge is not constantly tended; (b) The draw is normally in the fully open position, displaying flashing green lights to indicate that vessels may pass; (c) When a train approaches, the lights go to flashing red and a horn starts four blasts, pauses, and then continues four blasts. After an eight minute delay, the draw lowers and locks, providing the scanning equipment reveals nothing under the draw. The draw remains down for a period of eight minutes or while the approach track circuit is occupied; (d) After the train has cleared, the draw opens and the lights return to flashing green.

On January 12, 2004, the bridge owner, Florida East Coast Railroad, requested a deviation from the current operating regulations to allow the owner and operator to keep this bridge in the closed position during certain times each day to facilitate repairs. The Commander, Seventh Coast Guard District has granted a temporary