

withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

Dated: August 27, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-23891 Filed 9-18-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 Agri Laboratories, Ltd. The ANADA provides for the administration of an oxytetracycline injectable solution to cattle and swine for the treatment of various bacterial diseases.

DATES: This rule is effective September 19, 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: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200-128 that provides for the use of AGRIMYCIN 200 (oxytetracycline) Injection for the treatment of various bacterial diseases in cattle and swine. Agri Laboratories's AGRIMYCIN-200 Injection is approved as a generic copy of Pfizer's LIQUAMYCIN LA-200, approved under NADA 113-232. The ANADA is approved as of June 13, 2003, and the regulations are amended in 21 CFR 522.1660 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.

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 Subject in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1660 [Amended]

■ 2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (b) by numerically adding "057561"; and in paragraph (d)(1)(iii) in the second and ninth sentences by numerically adding "057561".

Dated: August 29, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-23942 Filed 9-18-03; 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; Salinomycin 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 an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides

for the use of single-ingredient Type A medicated articles containing salinomycin and chlortetracycline to make two-way combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective September 19, 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 68144, filed ANADA 200-357 for use of PENNCHLOR (chlortetracycline) and salinomycin Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler chickens. Pennfield Oil Co.'s ANADA 200 357 is approved as a generic copy of Alpharma, Inc.'s NADA 140-859. The ANADA is approved as of August 19, 2003, and the regulations are amended in 21 CFR 558.550 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.

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.

§ 558.550 [Amended]

■ 2. Section 558.550 *Salinomycin* is amended in paragraph (a)(3) by adding “and (d)(1)(xvi)” after “(d)(1)(xv)”; and in paragraph (d)(1)(xvi)(c) by removing “and 046573” and by adding in its place “and 053389”.

Dated: September 11, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–23996 Filed 9–18–03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[CGD08–03–033]

RIN 1625–AA09

Drawbridge Operation Regulation; Massalina Bayou, Panama City, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary rule.

SUMMARY: The Commander, Eighth Coast Guard District, has temporarily changed the regulation governing the operation of the Tarpon Dock bascule span drawbridge across Massalina Bayou, mile 0.0, at Panama City, Bay County, Florida. The regulation will allow the draw of the bridge to remain closed to navigation for one hour to facilitate the American Heart Walk.

DATES: This temporary rule is effective from 9 a.m. to 10 a.m. on October 18, 2003.

ADDRESSES: Documents referred to in this rule are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, 501 Magazine Street, New Orleans, Louisiana 70130–3396, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Eighth District Bridge Administration Branch maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, (504) 589–2965.

SUPPLEMENTARY INFORMATION:

Good Cause for Not Publishing an NPRM

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Thousands of pedestrians will cross the bridge during the event and this temporary rule is necessary to ensure their safety as they cross the bridge.

Background and Purpose

The City of Panama City has requested a temporary rule changing the operation of the Tarpon Dock bascule span drawbridge across Massalina Bayou, mile 0.0, in Panama City, Bay County, Florida. This temporary rule is needed to accommodate approximately 2,000 pedestrians that are expected to participate in a 3.5-mile walk. The bridge is near the beginning of the walk and allowing the bridge to open for navigation during this short time period would disrupt the event and could result in injury. The bridge has a vertical clearance of 7 feet above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. Navigation on the waterway consists primarily of commercial fishing vessels, sailing vessels and other recreational craft. Presently, Title 33, Code of Federal Regulations (CFR), § 117.301 states: The draw of the Tarpon Dock bascule span bridge, Massalina Bayou, mile 0.0, shall open on signal; except that from 9 p.m. until 11 p.m. on July 4, each year, the draw need not open for the passage of vessels. The draw will open at any time for a vessel in distress. This temporary rule will allow the bridge to be maintained in the closed-to-navigation position from 9 a.m. to 10 a.m. on October 18, 2003 to facilitate the American Heart Walk.

Regulatory Evaluation

This rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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 Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This temporary rule will be only one hour in duration and is therefore

expected to have only a minor effect on the local economy.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “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 of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this temporary rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit through the Tarpon dock bridge across Massalina Bayou during the closure. There is not expected to be a significant impact due to the short duration of the closure and the publicity given the event.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have