

animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) for bacitracin methylene disalicylate and streptomycin sulfate oral powder from Veterinary Specialties, Inc., to Alpharma Inc.

DATES: This rule is effective April 7, 2006.

FOR FURTHER INFORMATION CONTACT:

David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Veterinary Specialties, Inc., 387 North Valley Ct., Barrington, IL 60010, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 65-107 for ENTROMYCIN (bacitracin methylene disalicylate and streptomycin sulfate) Powder to Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024. Accordingly, the regulations are amended in 21 CFR 520.154b to reflect this change of sponsorship and a current format.

Following these changes of sponsorship, Veterinary Specialties, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Veterinary Specialties, Inc.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) remove the entry for

"Veterinary Specialties, Inc."; and in the table in paragraph (c)(2) remove the entry for "062925".

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. Revise § 520.154b to read as follows:

§ 520.154b Bacitracin methylene disalicylate and streptomycin sulfate powder.

(a) *Specifications.* Each gram of powder contains 200 units bacitracin methylene disalicylate and streptomycin sulfate equivalent to 20 milligrams of streptomycin.

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

(c) *Conditions of use in dogs—(1) Amount.* Administer 1 level teaspoonful per 10 pounds of body weight three times daily, mixed in a small quantity of liquid or feed.

(2) *Indications for use.* For the treatment of bacterial enteritis caused by pathogens susceptible to bacitracin and streptomycin such as *Escherichia coli*, *Proteus spp.*, *Staphylococcus spp.*, and *Streptococcus spp.*, and for the symptomatic treatment of associated diarrhea.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 30, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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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; 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 Pennfield Oil Co. that provides for a 0-day preslaughter withdrawal time following use of chlortetracycline in cattle feed.

DATES: This rule is effective April 7, 2006.

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: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed a supplement to NADA 138-935 for PENNCHLOR (chlortetracycline) Type A medicated articles used for making medicated feeds for the treatment of various bacterial diseases of livestock. The supplemental NADA provides for a 0-day withdrawal time before slaughter when Type C medicated feeds containing chlortetracycline are fed to cattle. The application is approved as of February 28, 2006, and the regulations are amended in 21 CFR 558.128 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 these applications 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 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.

§ 558.128 [Amended]

■ 2. In § 558.128, amend the table in paragraph (e)(4) in the "Limitations" column as follows:

■ a. In paragraph (ii), remove "To sponsor No. 046573: zero withdrawal time. To sponsor No. 053389: 1 d withdrawal time." and add in its place "To sponsor Nos. 046573 and 048164: zero withdrawal time.";

■ b. In paragraph (iv) in entry 1, remove "To sponsor No. 053389: 1 d withdrawal time. To sponsor No. 046573: zero withdrawal time." and add in its place "To sponsor Nos. 046573 and 048164: zero withdrawal time."; and

■ c. In paragraph (viii) in entries 1 and 2, remove "For sponsor 046573: zero withdrawal time. For sponsor 053389: 1 d withdrawal time." and add in its place "To sponsor Nos. 046573 and 048164: zero withdrawal time.".

Dated: March 30, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[CGD 11-06-002]

RIN 1625-AA08

Special Local Regulations for Marine Events; 2006 San Francisco Giants' Opening Night Fireworks Display, San Francisco Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations in the navigable waters of San Francisco Bay for the loading, transport, and launching of fireworks used during the 2006 San Francisco Giants' Opening Night Fireworks Display to be held on April 7, 2006. These special local regulations are intended to prohibit vessels and people from entering into or remaining within the regulated areas in order to ensure the safety of participants and spectators.

DATES: This rule is effective from 1 p.m. to 10 p.m. on April 7, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of the docket CGD 11-06-002 and are available for inspection

or copying at Coast Guard Sector San Francisco, 278 Yerba Buena Island, San Francisco, California 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Junior Grade Jennifer Green, U.S. Coast Guard Sector San Francisco, at (415) 556-2950 ext. 136.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, special local regulations are necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

For the same reasons listed in the previous paragraph, 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**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

Background and Purpose

The San Francisco Giants are sponsoring a brief fireworks display on April 7, 2006 in the waters of San Francisco Bay near AT&T Park. The fireworks display is meant for entertainment purposes as a finale to conclude the 2006 San Francisco Giants' Opening Night baseball game. These special local regulations are being issued to establish a temporary regulated area in San Francisco Bay around the fireworks launch barge during loading of the pyrotechnics, during the transit of the barge to the display location, and during the fireworks display. This regulated area around the launch barge is necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barge. The Coast Guard has granted the event sponsor a marine event permit for the fireworks display.

Discussion of Rule

The Coast Guard is establishing temporary special local regulations on specified waters off of the San Francisco waterfront. During the loading of the fireworks barge, while the barge is being towed to the display location, and until the start of the fireworks display, the special local regulations apply to the navigable waters around and under the fireworks barge within a radius of 100 feet. During the 15-minute fireworks display, the area to which these special local regulations apply will increase in size to encompass the navigable waters around and under the fireworks barge within a radius of 1,000 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 1 p.m. on April 7, 2006, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place between 5:30 p.m. and 7:30 p.m. on April 7, 2006. During the fireworks display, scheduled to commence at approximately 9:30 p.m., the fireworks barge will be located approximately 1,000 feet off of Pier 48 in position 37°46'57.2" N., 122°23'58.0" W.

The effect of the temporary special local regulations will be to restrict general navigation in the vicinity of the fireworks barge while the fireworks are loaded at Pier 50, during the transit of the fireworks barge, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area. These regulations are needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

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.

Although this regulation prevents traffic from transiting a portion of San Francisco Bay during the event, the effect of this regulation will not be significant due to the small size and limited duration of the regulated area. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing. We expect the economic impact of this