

**§ 520.1696b Penicillin G potassium in drinking water.**

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(b) *Sponsors.* See Nos. 046573, 053501, 059130, 059320, and 061623 in § 510.600(c) of this chapter.

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Dated: February 23, 2004.

**Stephen F. Sundlof,**  
 Director, Center for Veterinary Medicine.  
 [FR Doc. 04-4653 Filed 3-2-04; 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; Diclazuril**

**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 new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing diclazuril and roxarsone to formulate two-way

combination drug Type C medicated feeds for broiler chickens.

**DATES:** This rule is effective March 3, 2004.

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600, e-mail: *candres@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-223 for use of CLINACOX (diclazuril) and 3-NITRO (roxarsone) Type A medicated articles to formulate two-way combination drug Type C medicated feeds for broiler chickens. The NADA is approved as of January 27, 2004, and the regulations are amended in 21 CFR 558.198 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.

■ 2. Section 558.198 is amended in the table in paragraph (d)(1) by redesignating paragraphs (d)(1)(vi) and (d)(1)(vii) as paragraphs (d)(1)(vii) and (d)(1)(viii), respectively, and by adding new paragraph (d)(1)(vi) to read as follows:

**§ 558.198 Diclazuril.**

\* \* \* \* \*  
 (d) \* \* \*  
 (1) \* \* \*

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(vi) 0.91(1 ppm)	Roxarsone 22.7 to 45.4	Broiler chickens: As in item (i) of this table; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration throughout growing period. Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Roxarsone provided by No. 046573 in § 510.600(c) of this chapter.	046573
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Dated: February 23, 2004.

**Stephen F. Sundlof,**

Director, Center for Veterinary Medicine.

[FR Doc. 04-4654 Filed 3-2-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[CGD01-03-097]

RIN 1625-AA00

**Safety Zone; Paerdegat Basin, Belt Parkway Bridge Emergency Repairs, Brooklyn, NY**

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone 50 yards upstream and downstream of the Belt Parkway Bridge within Paerdegat Basin to aid completion of the Belt Parkway Bridge emergency repairs in Brooklyn, NY. This action is necessary to protect the maritime public from the hazards posed by the emergency repair efforts. The safety zone prohibits immediate entry into this portion of the Paerdegat Basin during the intermittent closure enforcement period.

**DATES:** This rule is effective from 8 a.m. on February 23, 2004 through 8 p.m. on March 26, 2004.

**ADDRESSES:** Documents indicated in this preamble are available in the docket are part of docket CGD01-03-097 and are available for inspection or copying at Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, room 203, Staten Island, NY 10305 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander W. Morton, Waterways Oversight Branch, Coast Guard Activities New York (718) 354-4191.

**SUPPLEMENTARY INFORMATION:****Regulatory Information**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this rule. Good cause exists for not publishing an NPRM and for making this regulation effective in less than 30 days after **Federal Register** publication. It has come to the attention of the Coast Guard that vessels cannot safely pass the barge that is to conduct

fendering repairs on the Belt Parkway Bridge. Repairs on the bridge fendering are scheduled to begin by February 2, 2004. Therefore, in order to ensure safe passage of vessels through the Belt Parkway Bridge, this regulation needs to be effective less than 30 days after publication in the **Federal Register**.

The Belt Parkway Bridge repairs were determined necessary as a result of a recent bridge allision. Waterway closures in the vicinity of and beneath the bridge are needed because repair equipment and construction materials will be in the vicinity of the bridge. Delaying this work for sufficient time to conduct a public notice rulemaking and advanced publication would be contrary to the public interest for safety purposes.

**Background and Purpose**

This rule is necessary to ensure the continued safe navigation under and through the Belt Parkway Bridge during fender repair operations. While repair operations are underway, a working barge will dramatically limit the ability of vessels to transit the waterway. However, the working barge will move on demand given one-hour notice by way of VHF CH 13.

The Captain of the Port anticipates minimal negative impact on vessel traffic due to this emergency repair work given the above schedule and ability to pass with notice.

**Discussion of Rule**

This rule establishes a safety zone on all waters of Paerdegat Basin 50-yards upstream and downstream of the Belt Parkway Bridge. The safety zone is in effect between 8 a.m. on February 23, 2004 through March 26, 2004 at 8 p.m. At all times, mariners can safely transit into, and out of, Paerdegat Basin, through the Belt Parkway Bridge, when a minimum of one-hour advance notice is given to the onscene vessel operator on VHF CH 13 between 7 a.m. and 3:30 p.m. Monday through Friday. The area will be opened for vessel transits after the stated working hours and on weekends. Public notifications will be made prior to the effective period via the Local Notice to Mariners, Marine Information and electronic mail Broadcasts, and on the Internet at <http://www.harborops.com>.

**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).

This finding is based on the following: Mariners utilizing Paerdegat Basin were notified of this closure and the one-hour delay of passage. Mariners held no objection based on the fact that they can safely transit into, and out of, Paerdegat Basin when a minimum of one-hour advance notice is given to the onscene vessel operator between 7 a.m. and 3:30 p.m. Monday through Friday during the brief repair period. Also, the area will be opened for vessel transits after working hours and on weekends. The local maritime community and public will be notified in advance of any work with regard to the closures by way of the Local Notice to Mariners, marine information and electronic mail broadcasts; and on the internet at <http://www.harborops.com>.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), the Coast Guard 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 rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the affected waterway during the time this zone is enforced.

This safety zone will not have a significant economic impact on a substantial number of small entities for reasons enumerated under the "Regulatory Evaluation" section.

**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 temporary rule so that we can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant Commander W. Morton, Waterways