

use of an injectable praziquantel solution in dogs and cats for the removal of various species of cestodes (tapeworms).

**DATES:** This rule is effective December 31, 2002.

**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](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-176 that provides for the veterinary prescription use of PRAZITECH (praziquantel) Injection in dogs and cats for the removal of various species of cestodes (tapeworms). Phoenix Scientific's PRAZITECH Injection is approved as a generic copy of Bayer Corp.'s DRONCIT 5.68% Injectable Solution, approved under NADA 111-607. The ANADA is approved as of October 16, 2002, and the regulations are amended in 21 CFR 522.1870 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 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 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.

**§ 522.1870 [Amended]**

2. Section 522.1870 *Praziquantel injectable solution* is amended in paragraph (b) by removing "Sponsor. See 000859" and by adding in its place "Sponsors. See Nos. 000859 and 059130".

Dated: December 18, 2002.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 117**

**[CGD 08-02-044]**

**RIN 2115-AE47**

**Drawbridge Operating Regulation; Mississippi River, Iowa and Illinois**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation governing the Crescent Railroad Drawbridge, Mile 481.4, Upper Mississippi River near Rock Island, Illinois. This deviation allows the drawbridge to open on signal if at least 6 hours advance notice is given during the 53 day period starting at 12:01 a.m., January 7, 2003 and ending at 12:01 a.m., March 1, 2003, Central Standard Time. This deviation is necessary to allow the bridge owner time for preventive maintenance that is essential to the continued safe operation of the drawbridge.

**DATES:** This temporary deviation is effective from 12:01 a.m., January 7, 2003 until 12:01 a.m., March 1, 2003.

**ADDRESSES:** Materials referred to in this notice are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Commander (obr), Eighth Coast Guard District, 1222 Spruce Street, St.

Louis, MO 63103-2832, between 8 a.m. and 4 p.m., Monday through Friday, except on Federal holidays. The Bridge Administration Branch maintains the public docket for this temporary deviation.

**FOR FURTHER INFORMATION CONTACT:**

Roger K. Wiebusch, Bridge Administrator, Commander (obr), Eighth Coast Guard District, 1222 Spruce Street, St. Louis, MO 63103-2832, (314) 539-3900, extension 2378.

**SUPPLEMENTARY INFORMATION:** The Burlington Northern Santa Fe (BNSF) Railroad requested a temporary deviation on December 2, 2002 for the operation of the Crescent Railroad Drawbridge, Mile 481.4, Upper Mississippi River near Rock Island, Illinois to allow the bridge owner time for preventive maintenance. The drawbridge operation regulations found at 33 CFR 117.5, require the drawbridge to open on signal. In order to perform required annual maintenance, the bridge will open on signal if at least 6 hours advance notice is given. This deviation allows the bridge to operate on a 6-hour advance notice to open for navigation for 53 days starting at 12:01 a.m., January 7, 2003 and ending at 12:01 a.m., March 1, 2003. This maintenance period was scheduled during the winter months to lessen the impact on vessel traffic which will increase when Lock Nos. 17 and 19 reopen on March 1, 2003.

The Crescent Railroad Drawbridge provides a vertical clearance of 25.7 feet above normal pool in the closed to navigation position. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. The drawbridge will be able to open for emergencies during this period. There are no alternate routes for waterway traffic to bypass the Crescent Railroad Drawbridge. This deviation has been coordinated with waterway users. No objections were received.

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: December 23, 2002.

**Roger K. Wiebusch,**

*Bridge Administrator.*

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