development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices.

The agency has determined under 21 CFR 25.30(k) 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 final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity effects). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation also is considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, OMB has determined that this final rule is not a major rule for purposes of congressional review. The establishment of a uniform compliance date does not impose either costs or benefits. For future labeling regulations, FDA will assess the costs and benefits of the uniform compliance date as well as the option of setting other dates.

Because FDA has issued this final rule without first publishing a general notice of proposed rulemaking, a final regulatory analysis is not required by the Regulatory Flexibility Act (5 U.S.C. 601–612). Nonetheless, the uniform compliance date does not impose any burden on small entities. The agency will assess the costs and benefits of setting alternative dates as part of the regulatory flexibility analyses of future labeling regulations.

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112 million. FDA has determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

This action is not intended to change existing requirements for compliance dates contained in final rules published before January 1, 2003. Therefore, all final FDA regulations published in the **Federal Register** before January 1, 2003, will still go into effect on the date stated in the respective final rule.

The agency generally encourages industry to comply with new labeling regulations as quickly as feasible, however. Thus, when industry members voluntarily change their labels, it is appropriate that they incorporate any new requirements that have been published as final regulations up to that time.

In rulemaking that began with publication of a proposal on April 15, 1996 (61 FR 16422), and ended with a final rule on December 24, 1996, FDA provided notice and an opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date. Receiving no comments objecting to this practice, FDA finds any further rulemaking unnecessary for establishment of the uniform compliance date. Nonetheless, under 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this uniform compliance date should be modified or revoked.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. After its review of any comments received to this final rule, FDA will either publish a document providing its conclusions concerning the comments or will initiate notice and comment rulemaking to modify or revoke the uniform compliance date established by this final rule.

The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 2003, and before December 31, 2004. Those regulations will specifically identify January 1, 2006, as their compliance date. All food products subject to the January 1, 2006, compliance date must comply with the appropriate regulations when initially introduced into interstate commerce on or after January 1, 2006. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2006, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 24, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–32978 Filed 12–30–02; 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; Praziquantel Injectable Solution

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 Phoenix Scientific, Inc. The ANADA provides for the veterinary prescription

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*.

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.

[FR Doc. 02–32848 Filed 12–30–02; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. 02–33019 Filed 12–30–02; 8:45 am]

BILLING CODE 4910–15–U