SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for an expanded dose range and revised indications for the use of clindamycin hydrochloride oral liquid in both dogs and cats for the treatment of certain bacterial diseases.

DATES: This rule is effective June 7, 2004.

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, St. Joseph, MO 64503, filed a supplement to ANADA 200–193 for Clindamycin Hydrochloride Oral Liquid. The supplemental ANADA provides for an expanded dose range and revised indications for the use of clindamycin hydrochloride oral liquid in both dogs and cats for the treatment of certain bacterial diseases. The supplemental application is approved as of April 21, 2004, and the regulations are amended in 21 CFR 520.447 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 Subjects in 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Section 520.447 is amended by revising paragraphs (b)(1) and (b)(2) to read as follows:

§ 520.447 Clindamycin liquid.

* * * * *

(b) * * *

(1) Nos. 000009 and 059130 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), (d)(2)(i)(A), and (d)(2)(ii)(A) of this section.

(2) No. 059079 for use as in paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), (d)(2)(i)(B), and (d)(2)(ii)(B) of this section.

* * * * *

Dated: May 19, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–12718 Filed 6–4–04; 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; Ivermectin and Clorsulon 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 a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for an increased period of protection from reinfection with three species of internal parasites following administration of an ivermectin and clorsulon injectable solution to cattle.

DATES: This rule is effective June 7, 2004.

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *janis.messenheimer@fda.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 140–833 for IVOMEC Plus (ivermectin and clorsulon) Injection for cattle. The application extends the period of persistent effectiveness for *Oesophagostomum radiatum* to 28 days after treatment, and for *Cooperia punctata* and *Trichostrongylus axei* to 21 days after treatment. A veal calf warning statement is being added because residue depletion data for this class of cattle has not been submitted to the application. The supplemental NADA is approved as of April 21, 2004, and 21 CFR 522.1193 is amended 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 21, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for the three species of parasites listed previously in this document.

FDA 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.

■ 2. Section 522.1193 is amended by revising paragraphs (d)(2) and (d)(3) to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei, Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis, H. lineatum*); lice (*Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: May 19, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–12717 Filed 6–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–027]

RIN 1625–AA09

Drawbridge Operation Regulations: Chelsea River, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of the P.J. McArdle Bridge, mile 0.3, across the Chelsea River between East Boston and Chelsea, Massachusetts. This final rule will allow the bridge to remain in the closed position from 10 a.m. to 5 p.m. on June 5, 2004, to facilitate the First Annual Chelsea River Revel 5K Road Race. Vessels that can pass under the bridge without a bridge opening may do so at all times.

DATES: This rule is effective only on June 5, 2004.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD01–04–027] and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, One South Street, New York, New York, 10004, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (212) 668–7165. The First Coast Guard District, Bridge Branch, maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Arca, Project Officer, First Coast Guard District, (212) 668–7069.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 27, 2004, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Chelsea River, Massachusetts, in the **Federal Register** (69 FR 22749). We received no comment letters in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**.

The Coast Guard did not receive the bridge owner's request to close the bridge until March 16, 2004; therefore, taking into consideration the time for the NPRM, it is necessary to make this rule effective in less than 30 days in order to allow the event to take place as scheduled on June 5, 2004. The Coast Guard believes this is reasonable because the bridge must remain closed during the running of the First Annual Chelsea River Revel 5K Road Race in the interest of public safety.

Background and Purpose

The P.J. McArdle Bridge has a vertical clearance of 21 feet at mean high water and 30 feet at mean low water in the closed position. The existing drawbridge operation regulations listed at 33 CFR § 117.593 require the bridge to open on signal at all times.

The owner of the bridge, the City of Boston, requested a temporary change to the drawbridge operation regulations to allow the bridge to remain in the closed position from 10 a.m. to 5 p.m. on June 5, 2004, to facilitate the running of the First Annual Chelsea River Revel 5K Road Race. Vessels that can pass under the bridge without a bridge opening may do so at all times.

The Chelsea River is predominantly transited by commercial tugs, barges, and oil tankers. The Coast Guard coordinated this closure with the mariners that normally use this waterway and no objections were received.

The Coast Guard did not receive the request to keep the bridge closed to facilitate the scheduled road race until March 16, 2004. A shortened comment period was necessary, due the short notice given to the Coast Guard, to allow this final rule to become effective in time for the start of First Annual Chelsea River Revel 5K Road Race on June 5, 2004.

The Coast Guard believes this final rule is needed in order to provide for public safety and the safety of the race participants.

Discussion of Comments and Changes

The Coast Guard received no comments in response to our notice of proposed rulemaking. No changes have been made to this final rule.

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