(3) *Limitations.* Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 9, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19125 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Enrofloxacin 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 a supplemental new animal drug application (NADA) filed by Bayer Corp., Agriculture Div., Animal Health. The supplemental NADA provides for revised indications for use of enrofloxacin injectable solution in dogs for the management of diseases associated with bacteria susceptible to enrofloxacin.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Div., Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140–913 Baytril Injectable Solution (22.7 milligrams enrofloxacin per milliliter) to provide for revised indications for use of enrofloxacin for dogs for management of diseases associated with bacteria susceptible to enrofloxacin. The supplemental NADA is approved as of June 19, 1997. The basis of approval is discussed in the freedom of information summary.

The regulations are amended in § 522.812 (21 CFR 522.812) by redesignating paragraph (c) as paragraph (d) and by reserving paragraph (c) to provide for more uniform regulations and future expansion. Newly redesignated § 522.812(d)(2) is revised to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.812 is amended by redesignating existing paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraph (d)(2) to read as follows:

§ 522.812 Enrofloxacin solution.

* * * * *

(c) [Reserved]

(d) * * *

(2) *Indications for use.* Dogs for management of diseases associated with bacteria susceptible to enrofloxacin.

* * * * *

Dated: July 9, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19126 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin

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 Merck Research Laboratories, Division of Merck & Co., Inc. The supplemental NADA provides for topical use of ivermectin for control of infections of gastrointestinal roundworms for 14 days following use on cattle.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed supplemental NADA 140–841 that provides for the use of Ivomec® pour-on (5 milligrams of ivermectin per milliliter) for cattle to control infections of gastrointestinal roundworms *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment. The supplemental NADA is approved as of June 5, 1997, and the regulations are amended in 21 CFR 524.1193(d)(2) 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 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning June 5, 1997, because the supplement

contains substantial evidence of effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the additional indications.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 524.1193 [Amended]

2. Section 524.1193 *Ivermectin pour-on* is amended by adding to the end of paragraph (d)(2) the sentence ''It is also used to control infections of gastrointestinal roundworms *O. ostertagi, O. radiatum, H. placei, T. axei, Cooperia punctata,* and *C. oncophora* for 14 days after treatment.''

Dated: July 8, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19124 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05–97–013]

RIN 2115–AE47

Drawbridge Operation Regulations; Isle of Wight Bay, Ocean City, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the Maryland Department of Transportation (MDOT), the Coast Guard is changing the regulations that govern the operation of the Route 50 drawbridge across Isle of Wight Bay, mile 0.5, located in Ocean City, Maryland, by requiring restricted drawbridge openings for all vessels each Saturday between May 25 through September 15, between the hours of 1 p.m. to 5 p.m. During these times, the bridge need open only on the hour, and must remain in the open position until all waiting vessels pass. All other provisions of the existing regulation for the Route 50 bridge remain the same. This final rule will help reduce motor vehicle traffic delays and congestion related to summer traffic entering and exiting the town of Ocean City, while still providing for the reasonable needs of navigation.

EFFECTIVE DATE: This rule is effective on July 18, 1997.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection and copying at the Office of the Commander (Aowb), USCG Atlantic Area, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398–6222.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, USCG Atlantic Area, at (757) 398–6222.

SUPPLEMENTARY INFORMATION:

Regulatory History

On April 21, 1997, the Coast Guard published a notice of proposed rulemaking entitled Drawbridge Operation Regulations; Isle of Wright Bay, Ocean City, Maryland in the **Federal Register** (62 FR 19245). The comment period ended June 20, 1997. The Coast Guard received no comments on the proposed rulemaking. No public hearing was requested, and none was held.

Background and Purpose

The drawbridge across Isle of Wight Bay, mile 0.5 Ocean City, Maryland, is currently required to open on signal, except that, from October 1 through April 30 from 6 p.m. to 6 a.m., the draw shall open if at least three hours notice is given and, from may 25 through September 15 from 9:25 a.m. to 9:55 p.m. the draw shall open at 25 minutes and 55 minutes after the hour for a maximum of 5 minutes to permit accumulated vessels to pass.

The Maryland Department of Transportation's (MDOT) original request to change the existing regulation was based on a large number of vacationers traveling to and from Ocean City on Saturday afternoons during the tourist season (summer months). Vacationers check in and out of hotels on Ocean City Island every Saturday afternoon of the season. This creates a traffic surge of vehicles entering and exiting the island with only two highway bridges (Route 50 and Route 90) available for access. The Route 90 bridge is a fixed-span structure, and the Route 50 bridge is a drawbridge. Over 350 charter boats regularly pass through the Route 50 drawbridge. This produces a dilemma to both waterway users and vehicular traffic trying to access the same drawbridge. MDOT requested hourly openings on Saturday afternoons as opposed to the current half-hourly openings, in order to help reduce vehicular traffic congestion on U.S. 50 and thereby improve highway safety. MDOT requested a change in the operating schedule to reduce the number of times the bridge must open on signal. The new schedule would restrict drawbridge openings for all vessels every Saturday between May 25 through September 15, between the hours of 1 p.m. to 5 p.m. During these times, the bridge need open only on the hour, and must remain in the open position until all waiting vessels pass. The Coast Guard tested this change through a temporary deviation, which modified the opening schedule from July 13 through August 31, 1996. The test was intended to determine whether the Coast Guard should change the regulation to better balance the needs of both waterway users and vehicular traffic. Following the test, no comments were received. The Coast Guard contacted MDOT, the local Police Department and the US 50 bridge tenders. Based on their information the test did not create any undue hardships for waterway users, yet the hourly closures substantially improved highway conditions.

Discussion of Comments and Changes

The Coast Guard received no comments on the proposed rulemaking. Therefore, the proposed rule is being implemented without change.

Good Cause Statement

This final rule is effective in less than 30 days because it is contrary to the public interest to delay the effective date. Immediate action is required to alleviate the overwhelming traffic congestion caused by tourists who are prevented from entering and exiting Ocean City, Maryland while the Route 50 drawbridge is in the open position.