

lungworms, grubs, lice, and mange mites infections.

EFFECTIVE DATE: March 27, 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, is sponsor of NADA 128-409, which provides for the use of Ivomec® Injection (1% ivermectin) for cattle for the treatment and control of gastrointestinal roundworm, lungworm, grub, lice, and mange mite infections. The supplement provides for control of infections of *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment, and *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, *C. oncophora*, and *Oesophagostomum radiatum* for 14 days after treatment. The supplement is approved as of February 24, 1997, and the regulations are amended in 21 CFR 522.1192(d)(2)(ii) 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)), approval of this supplement qualifies for 3 years of marketing exclusivity beginning February 24, 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 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).

§ 522.1192 [Amended]

2. Section 522.1192 *Ivermectin injection* is amended in paragraph (d)(2)(ii) by adding to the end of the paragraph the sentence "It is also used to control infections of *D. viviparus* and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *Oesophagostomum radiatum* for 14 days after treatment."

Dated: March 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-7789 Filed 3-26-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD8-95-026]

Drawbridge Operation Regulation; Bonfouca Bayou, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the regulation governing the operation of the swing span drawbridge across Bonfouca Bayou, mile 7.0, at Slidell, St. Tammany Parish, Louisiana. A notice of proposed rulemaking was published on May 1, 1996, and a supplemental notice of proposed rulemaking (SNPRM) was published on December 27, 1996, because of comment received. This final rule maintains the operating times published in the SPRM to which no comments were received.

DATES: This regulation becomes effective on April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Phil Johnson, Bridge Administration Branch, Eighth Coast Guard District, telephone (504) 589-2965.

SUPPLEMENTARY INFORMATION:

Regulatory History

The Coast Guard published a notice of proposed rulemaking [61 FR 19223] on Wednesday, May 1, 1996. Comments received prompted the Coast Guard to reevaluate the proposed rule. Mariners and business owners, located upstream of the bridge commented on the proposal, stating that their business would suffer if vessels were not permitted to transit above the periods of three continuous hours. Additionally, local commercial marine interests requested that the draw open on demand from 9 p.m. to 5 a.m. if at least 4 hours advance notice is given, in lieu of 12 hours notice. Subsequently, a notice of supplemental proposed rulemaking along with a notice of temporary deviation was published Friday, December 27, 1996 [61 FR 68198] incorporating changes in the proposed rule. No comments were received on the latter notice. Accordingly, the Coast Guard will maintain the operating times as noted in the notice of supplemental proposed rulemaking.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" may include (1) small businesses and non-for-profit organizations that are independently owned and operated and are not dominant in their field and (2) governmental jurisdictions with populations of less than 50,000.

Since this final rule was revised in response to comments, concerns and suggestions of local mariners and maritime business interests, the economic impact of this final rule is expected to be minimal. Therefore, the Coast Guard certifies under 5 U.S.C.

604(b) that this rulemaking will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This final rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 and it has been determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under paragraph 2.B.2.g(5) of Commandant Instruction M16475.1B, this rulemaking is categorically excluded from further environmental documentation. A "Categorical Exclusion Determination" has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, Part 117 of Title 33, Code of Federal Regulations, is amended as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.433 is revised to read as follows:

§ 117.433 Bonfouca Bayou.

The draw of the S433 bridge, mile 7.0, at Slidell, shall operate as follows:

(a) The draw need not open for passage of vessels from 7 a.m. to 8 a.m. and from 1:45 p.m. to 2:45 p.m., Monday through Friday except Federal Holidays.

(b) The draw need open only on the hour and half-hour from 6 a.m. to 7 a.m. and from 3 p.m. to 6 p.m., Monday through Friday except Federal holidays.

(c) The draw shall open a signal from 9 p.m. to 5 a.m., if at least 4 hours notice is given to the Louisiana Department of Transportation and Development Security Service at (504) 375–0100.

(d) At all other times the draw shall open on signal.

Dated: March 7, 1997.

T.W. Josiah,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 97–7730 Filed 3–26–97; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 162

[CGD09–97–005]

Temporary Speed Limits for the St. Marys River

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is making a temporary amendment to the speed limits for the St. Marys River during the 1996–97 icebreaking season. This amendment reduces the speed limit by 2 miles per hour through that part of the system, between Munuscong Channel Lighted Buoy 8 (LLNR 13065) and Lake Nicolet Light 80 (LLNR 13465) upbound and between Lake Nicolet Light 80 (LLNR 13465) and West Neebish Channel Light 9 (LLNR 13715) downbound. These temporary changes to the speed regulations are a precautionary measure to minimize any possible damage to the environment due to movement of large commercial vessels through the ice.

DATES: This regulation is effective from March 13, 1997, through April 15, 1997.

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) John Marian, U.S. Coast Guard, Group Sault Ste. Marie, 337 Water Street, Sault Ste. Marie, Michigan, 49783, (906) 635–3303.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a Notice of Proposed Rulemaking has not been published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Publication of a notice of proposed rulemaking and delay in the effective date would be contrary to the public interest because immediate action is necessary to prevent possible damage to the environment.

Discussion of Proposed Regulation

In a letter received on February 26, 1993, the Michigan Department of Natural Resources advised the Commander of the Ninth Coast Guard District of concerns over the environmental impact of ship transits through the St. Marys River during the period of March 21 to April 1. March 25 is the fix date for the opening of the locks at Sault Ste. Marie, which allows large commercial shipping access to the

St. Marys River from Lake Superior. In accordance with an agreement reached on June 29, 1993, with the U.S. Army Corps of Engineers, the U.S. Fish and Wildlife Service and the Michigan Department of Natural Resources, the Commander of the Ninth Coast Guard District is making this temporary change to the speed regulations during periods when ice breaking is being conducted in the vicinity of Neebish Island, St. Mary's River, Michigan. This speed reduction is a precautionary measure to minimize possible damage to the environment. The speed limit is being reduced by 2 statute miles per hour in the area between Munuscong Channel Lighted Buoy 8 (LLNR 13065) and Lake Nicolet Light 80 (LLNR 13465), upbound, and between Lake Nicolet Lighted Buoy 80 (LLNR 13465) and West Neebish Channel Light 9 (LLNR 13715), downbound. The West Neebish Channel Light 9 checkpoint has been added to extend the reduced speed limit area past Winter Point, thereby protecting the sensitive environment between Winter Point and West Neebish Channel Light 9. Speed limits apply to the average speed between established reporting points.

Federalism Implications

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

A recent environmental impact study by the United States Army Corps of Engineers indicated that March 21 is the optimal opening date of the locks at Sault Ste. Marie. [see U.S. Army Corps of Engineers Draft Environmental Impact Statement, Opening Operations of the Lock Facilities on March 21 (February 1993), Supplement III to the Final Environmental Impact Statement, Operations, Maintenance, and Minor Improvements of the Federal Facilities at Sault Ste. Marie, Michigan (July 1997)]. The same study by the Corps of Engineers indicates that there is no significant impact on fish populations due to movement of large commercial vessels through the ice. However, the Michigan Department of Natural Resources asserts that there may be such an impact during the early period of March 21 to April 1. The Ninth Coast Guard District has adopted the U.S. Army Corps of Engineers EIS, EIS Supplements, and EIS studies on Operations, Maintenance, and Minor Improvements of the Federal Facilities