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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Airspace Docket No. 97-AWP-4]

Adding Controlling Agency to Restricted Areas: R-2530 Sierra Army Depot, CA; R-4802 Lone Rock, NV; and R-4811 Hawthorne, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action adds "FAA, Oakland Air Route Traffic Control Center (ARTCC)" as the controlling agency for Restricted Areas 2530 (R-2530), Sierra Army Depot, CA; R-4802, Lone Rock, NV; and R-4811, Hawthorne, NV, to support the provisions of the Open Skies Treaty. This is an administrative change, therefore, there are no changes to the boundaries, designated altitudes, times of designation, or activities conducted within the affected restricted area.

EFFECTIVE DATE: 0901 UTC, May 22, 1997.

FOR FURTHER INFORMATION CONTACT: William C. Nelson, Airspace and Rules Division, ATA-400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

The Rule

This amendment to part 73 of the Federal Aviation Regulations (14 CFR part 73) adds "FAA, Oakland ARTCC" as the controlling agency for R-2530 Sierra Army Depot, CA, R-4802 Lone Rock, NV, and R-4811 Hawthorne, NV, to support the provisions of the Open Skies Treaty. This amendment is an administrative change, therefore, there

are no changes to the boundaries, designated altitudes, times of designation, or activities conducted within the affected restricted area. Because this action is a minor technical amendment in which the public is not particularly interested, I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Sections 73.25 and 73.48 of part 73 of the Federal Aviation Regulations were republished in FAA Order 7400.8D dated July 11, 1996.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This action adds a controlling agency to the specified restricted areas. There are no changes to the boundaries, designated altitudes, times of designation, or activities conducted within the affected restricted areas. Accordingly, this action is not subject to environmental assessments and procedures as set forth in FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts" and the National Environmental Policy Act of 1969.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.25 [Amended]

2. Section 73.25 is amended as follows:

R-2530 Sierra Army Depot, CA [Amended]

By adding the following controlling agency: "Controlling agency. FAA, Oakland ARTCC."

§ 73.48 [Amended]

3. Section 73.48 is amended as follows:

R-4802 Lone Rock, NV [Amended]

By adding the following controlling agency: "Controlling agency. FAA, Oakland ARTCC."

R-4811 Hawthorne, NV [Amended]

By adding the following controlling agency: "Controlling agency. FAA, Oakland ARTCC."

Issued in Washington, DC, on March 19, 1997.

Jeff Griffith,

Program Director for Air Traffic Airspace Management.

[FR Doc. 97-7825 Filed 3-26-97; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable 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 persistent control of gastrointestinal roundworms and lungworms following use of ivermectin injection for cattle for treatment and control of certain harmful gastrointestinal roundworms,

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]

BILLING CODE 4160-01-F

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.