

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 97-22131 Filed 8-20-97; 8:45 am]

BILLING CODE 7905-01-P-M

RAILROAD RETIREMENT BOARD

20 CFR Part 367

RIN 3220-AB26

Collection of Debts

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) amends its regulations pertaining to the collection of debts by offset against Federal payments to reflect amendments to section 3716 of Title 31 by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134).

DATES: Effective Date: This Regulation will be effective August 21, 1997.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Michael C. Litt, General Attorney, Bureau of Law, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611, (312) 751-4929, TDD (312) 751-4701.

SUPPLEMENTARY INFORMATION: Part 367 of the Board's regulations provides for the collection of debts by administrative offset under the authority of the Debt Collection Act of 1982, 31 U.S.C. 3716. The Debt Collection Improvement Act of 1996 (Pub. L. 104-134) amended 31 U.S.C. 3716 to provide for referral of delinquent Federal nontax debts to the Department of Treasury for administrative offset ("Treasury Offset Program"), and to provide for the mandatory referral of such debts over 180 days delinquent to the Treasury Offset Program, subject to certain exceptions. Accordingly, the Board amends this part to implement the provisions of Public Law 104-134.

Section 367.1 is revised to cite the authority of Public Law 104-134 and its provision for the referral of delinquent Federal nontax debts to the Treasury Offset Program.

Section 367.2 is amended to provide that only nontax debts will be referred to the Treasury Offset Program, and that a debt will not be referred if the Board's records show that foreclosure is pending on collateral securing the debt or if the debt has been referred to the Department of Justice or is otherwise in litigation with the Board.

Section 367.3 is amended to provide that the Board shall refer nontax debts over 10 days delinquent to the Treasury Offset Program and that in cases of mandatory referral of delinquent debt, unless otherwise directed by the Secretary of Treasury, the Board is not required to determine whether administrative offset is feasible, allowable, and appropriate.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866. Therefore, no regulatory impact analysis is required. There are no new information collections associated with this rule.

The Board published this rule as an interim final rule on April 21, 1997 (62 FR 19219) and comments were invited by June 20, 1997. No Comments were received. Accordingly, the interim final rule is adopted as a final rule without change.

Dated: August 12, 1997.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 97-22130 Filed 8-20-97; 8:45 am]

BILLING CODE 7905-01-P-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Doramectin

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 Pfizer, Inc. The supplemental NADA provides for use of doramectin in cattle to control infections and to protect from reinfection with *Cooperia punctata* and *Dictyocaulus viviparus* for 28 days after treatment. This supplemental NADA also amends the wording of the claim for protection against infection or reinfection with *Ostertagia ostertagi* for 21 days and incorporates the claim into the new indication statement.

EFFECTIVE DATE: August 21, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV-135), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, is sponsor of NADA 141-061 that provides for the use of Dectomax® 1% injectable solution (doramectin) for treatment and control of certain gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, and mange mites of cattle, and protection against infection or reinfection with *O. ostertagi* for up to 21 days. The firm filed a supplemental NADA that provides for added use in cattle to control infections and to protect from reinfection with *C. punctata* and *D. viviparus* for 28 days after treatment. The supplemental NADA also amends the wording of the claim for " * * * protection against infection or reinfection with *Ostertagia ostertagi* for 21 days" and incorporates the claim into the new indication statement. The supplemental NADA is approved as of July 18, 1997, and the regulations are amended in 21 CFR 522.770(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 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, from 9 a.m. to 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning July 18, 1997, because the supplement contains substantial evidence of the effectiveness of the drug involved, 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 added indication to control infections and to protect cattle from reinfection with *C. punctata* and *D. viviparus* for 28 days after treatment.

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).

2. Section 522.770 is amended by revising paragraph (d)(2) to read as follows:

§ 522.770 Doramectin.

* * * * *

(d) * * *

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, and mange mites. To effectively control infections and to protect cattle from reinfection with *Ostertagia ostertagi* for 21 days, and *Cooperia punctata* and *Dictyocaulus viviparus* for 28 days after treatment.

* * * * *

Dated: August 1, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-22264 Filed 8-20-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 100**

[CGD08-97-026]

RIN 2115-AE46

Special Local Regulation; Riverfest, Cumberland River Mile 126.5 to 128.5, Clarksville, Tennessee

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: A temporary special local regulation is being adopted for the Riverfest. This event will be held on September 7, 1997 from 8 a.m. until 6 p.m. at the riverfront in Clarksville, Tennessee. This regulation is needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATE: This temporary regulation is effective from 8 a.m. until 6 p.m. on September 7, 1997.

FOR FURTHER INFORMATION CONTACT:

LTJG Tom Tarrants, Marine Safety Office, Paducah, KY Tel: (502) 442-1621.

SUPPLEMENTARY INFORMATION:**Regulatory History**

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking for this regulation has not been published, and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impracticable. The details of the event were not finalized until July 24, 1997, and there was not sufficient time remaining to publish a proposed rule in advance of the event or to provide for a delayed effective date.

Background and Purpose

The marine event requiring this regulation includes boat drag races on the Cumberland River. The event is sponsored by the City of Clarksville. Spectators will be able to view the event from areas designated by the sponsor. Non-participating vessels will be able to transit the area after each race has ended.

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 costs 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 because of the event's short duration.

Small Entities

The Coast Guard finds that the impact on small entities, if any, is not substantial. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this temporary rule will not have a significant economic impact on a substantial number of small entities because of the event's short duration.

Collection of Information

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

Federalism Assessment

The Coast Guard has analyzed this action in accordance with the principles and criteria of Executive Order 12612 and has determined that this rule does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2.C. of Commandant Instruction M16475.1B (as revised by 61 FR 13563; March 27, 1996), this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements.

Temporary Regulation

In consideration of the foregoing, part 100 of title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary section 100.35-T08-026 is added to read as follows:

§ 100.35-T08-026 Cumberland River, Clarksville, Tennessee.

(a) *Regulated Area:* Cumberland River Mile 126.5 to 128.5.

(b) *Special Local Regulation:* All persons and/or vessels not registered with the sponsors as participants or official patrol vessels are considered spectators. The "official patrol" consists of any Coast Guard, public, state or local law enforcement and/or sponsor provided vessels assigned to patrol the event.

(1) No spectators shall anchor, block, loiter in, or impede the through transit of participants or official patrol vessels in the regulated area during effective dates and times, unless cleared for such entry by or through an official patrol vessel.

(2) When hailed and/or signaled by an official patrol vessel, a spectator shall come to an immediate stop. Vessels shall comply with all directions given. Failure to comply may result in the issuance of a citation.

(3) The Coast Guard Patrol Commander is empowered to forbid and control the movement of all vessels in the regulated area. The Patrol Commander may terminate the event at