

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 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

##### 21 CFR Part 522

Animal drugs.

##### 21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are 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. New § 522.770 is added to read as follows:

##### **§ 522.770 Doramectin.**

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 000069 in § 510.600 (c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use. Cattle—(1) Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, and mange mites, and protection against infection or

reinfection with *Ostertagia ostertagia* for up to 21 days.

(3) *Limitations.* Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

#### **PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.225 is added to subpart B to read as follows:

##### **§ 556.225 Doramectin.**

A tolerance of 0.1 part per million is established for parent doramectin (marker residue) in liver (target tissue) of cattle.

Dated: September 23, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-26212 Filed 10-10-96; 8:45 am]

BILLING CODE 4160-01-F

#### **DEPARTMENT OF TRANSPORTATION**

##### **Coast Guard**

##### **33 CFR Part 100**

[CGD 05-96-086]

RIN-AE84

##### **Special Local Regulations for Marine Events; Atlantic Ocean, Ocean City, MD**

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

**SUMMARY:** This document implements regulations for the Ocean City Offshore Grand Prix, a marine event to be held on October 13, 1996 in the Atlantic Ocean off of Ocean City, Maryland. These special local regulations are needed to provide for the safety of the participants and spectators on navigable waters during this event. This rule will restrict general navigation in the regulated area.

**EFFECTIVE DATES:** 33 CFR 100.517 is effective from 11 a.m. to 4 p.m., October 13, 1996. If the event is postponed due to weather conditions, 33 CFR 100.517 is effective from 11 a.m. to 4 p.m., October 14, 1996.

**FOR FURTHER INFORMATION CONTACT:** BMCM Niblett, marine events

coordinator, Commander, Coast Guard Group Eastern Shore, Chincoteague, Virginia 23336-1510, (804) 336-2833.

**SUPPLEMENTARY INFORMATION:** On October 13, 1996, the United States Offshore Racing Association will hold the Ocean City Offshore Grand Prix in the Atlantic Ocean off of Ocean City, Maryland. The event will consist of approximately forty to sixty powerboats, ranging from 24 to 50 feet in length, racing on a designated course within the regulated area described in 33 CFR 100.517(a). To enhance the safety of the participants and spectators, 33 CFR 100.517 will be in effect during this event. Under provisions of 33 CFR 100.517, a vessel may not enter the regulated area unless it receives permission from the Coast Guard patrol commander. These restrictions will be in effect for a limited period and should not result in significant disruption of maritime traffic. The Coast Guard patrol commander will announce the specific periods during which the restrictions will be enforced.

Dated: September 23, 1996.

Kent H. Williams,

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. 96-26151 Filed 10-10-96; 8:45 am]

BILLING CODE 4910-14-M

##### **33 CFR Part 100**

[CGD08-96-041]

RIN 2115-AE46

##### **Special Local Regulation; Big River Rendezvous, Mississippi River Mile 483.0-493.0**

AGENCY: Coast Guard, DOT.

ACTION: Temporary Final Rule.

**SUMMARY:** A special local regulation is being adopted for the Big River Rendezvous which will be held on the Mississippi River in Davenport, IA on October 10-13, 1996. The sponsor of this event is the Scott County Sesquicentennial Association. This regulation is needed to control vessel traffic in the vicinity of the event. The regulation will restrict general navigation in the regulated area for the safety of spectators, participants and commercial traffic.

**EFFECTIVE DATES:** This regulation is effective on October 10-14, 1996.

**FOR FURTHER INFORMATION CONTACT:** LT R. G. Moulton, Supervisor, Designated Patrol Commander, U.S. Coast Guard, MSD Quad Cities, Rock Island Arsenal Bldg 218, P.O. Box 3220, Rock Island, IL 61204. The telephone