(g) *Refillable:* It is deceptive to misrepresent, directly or by implication, that a package is refillable. An unqualified refillable claim should not be asserted unless a system is provided for the collection and return of the package for refill or the later refill of the package by consumers with product subsequently sold in another package. A package should not be marketed with an unqualified refillable claim, if it is up to the consumer to find new ways to refill the package.

Example 1: A container is labeled ''refillable x times.'' The manufacturer has the capability to refill returned containers and can show that the container will withstand being refilled at least x times. The manufacturer, however, has established no collection program. The unqualified claim is deceptive because there is no means for collection and return of the container to the manufacturer for refill.

Example 2: A bottle of fabric softener states that it is in a ''handy refillable container.'' The manufacturer also sells a large-sized container that indicates that the consumer is expected to use it to refill the smaller container. The manufacturer sells the large-sized container in the same market areas where it sells the small container. The claim is not deceptive because there is a means for consumers to refill the smaller container from larger containers of the same product.

(h) *Ozone safe and ozone friendly:* It is deceptive to misrepresent, directly or by implication, that a product is safe for or ''friendly'' to the ozone layer or the atmosphere. For example, a claim that a product does not harm the ozone layer is deceptive if the product contains an ozone-depleting substance.

Example 1: A product is labeled ''ozone friendly.'' The claim is deceptive if the product contains any ozone-depleting substance, including those substances listed as Class I or Class II chemicals in Title VI of the Clean Air Act Amendments of 1990, Public Law 101–549, and others subsequently designated by EPA as ozone-depleting substances. Chemicals that have been listed or designated as Class I are chlorofluorocarbons (CFCs), halons, carbon tetrachloride, 1,1,1-trichloroethane, methyl bromide and hydrobromofluorocarbons (HBFCs). Chemicals that have been listed as Class II are hydrochlorofluorocarbons (HCFCs).

Example 2: An aerosol air freshener is labeled ''ozone friendly.'' Some of the product's ingredients are volatile organic compounds (VOCs) that may cause smog by contributing to ground-level ozone formation. The claim is likely to convey to consumers that the product is safe for the atmosphere as a whole, and is therefore, deceptive.

Example 3: The seller of an aerosol product makes an unqualified claim that its product ''Contains no CFCs.'' Although the product does not contain CFCs, it does contain HCFC–22, another ozone depleting ingredient. Because the claim ''Contains no CFCs'' may imply to reasonable consumers that the product does not harm the ozone layer, the claim is deceptive.

Example 4: A product is labeled ''This product is 95% less damaging to the ozone layer than past formulations that contained CFCs.'' The manufacturer has substituted HCFCs for CFC–12, and can substantiate that this substitution will result in 95% less ozone depletion. The qualified comparative claim is not likely to be deceptive.

§ 260.8 Environmental assessment.

National Environmental Policy Act. In accordance with § 1.83 of the FTC's Procedures and Rules of Practice [4] and § 1501.3 of the Council on Environmental Quality's regulations for implementing the procedural provisions of National Environmental Policy Act, 42 U.S.C. 4321 *et seq.* (1969),[5] the Commission prepared an environmental assessment when the guides were issued in July 1992 for purposes of providing sufficient evidence and analysis to determine whether issuing the Guides for the Use of Environmental Marketing Claims required preparation of an environmental impact statement or a finding of no significant impact. After careful study, the Commission concluded that issuance of the Guides would not have a significant impact on the environment and that any such impact ''would be so uncertain that environmental analysis would be based on speculation.'' [6] The Commission concluded that an environmental impact statement was therefore not required. The Commission based its conclusions on the findings in the environmental assessment that issuance of the guides would have no quantifiable environmental impact because the guides are voluntary in nature, do not preempt inconsistent state laws, are based on the FTC's deception policy, and, when used in conjunction with the Commission's policy of case-by-case enforcement, are intended to aid compliance with section 5(a) of the FTC Act as that Act applies to environmental marketing claims.

The Commission has concluded that modifications to the guides in this part will not have a significant effect on the environment, for the same reasons that the issuance of the original guides in 1992 was deemed not to have a significant effect on the environment. Therefore, the Commission concludes that an environmental impact statement is not required in conjunction with the 1996 modifications to the Guides for the Use of Environmental Marketing Claims.

[4] 16 CFR 1.83.

[5] 40 CFR 1501.3.

[6] 16 CFR 1.83(a).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–25938 Filed 10–10–96; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; 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 new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for subcutaneous and intramuscular use of doramectin for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, and mange mites in cattle.

EFFECTIVE DATE: October 11, 1996.

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: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is sponsor of NADA 141–061, which provides for the use of Dectomax® 1 percent injectable solution (doramectin) for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, and mange mites in cattle. The NADA is approved as of July 30, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.770 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, part 556 (21 CFR part 556) is amended by adding new § 556.225 to provide for tolerances for residues of doramectin in edible cattle tissues.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 30, 1996, because no active ingredient (including any ester or salt of the active ingredient) has been previously approved in any other application filed under section 512(b)(1) of the act.

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