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Dated: Approved by the Commission on June 28, 2001.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 01-16932 Filed 7-5-01; 8:45 am]
BILLING CODE 6750-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Clorsulon

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 Merial Ltd. The supplemental NADA provides for establishing a tolerance for residues of clorsulon in the muscle tissue of cattle.

DATES: This rule is effective July 6, 2001.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, filed a supplement to NADA 136-742 that provides for the use of Curatrem® (clorsulon) Drench in cattle for the treatment of liver fluke infestations. The supplement provides for establishing a tolerance for residues of clorsulon in the muscle tissue of cattle. The supplement is approved as of May 16, 2001, and § 556.163 (21 CFR 556.163) is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 556.163 is further amended by deleting references to safe concentrations and by adding the previously established acceptable daily intake of total residues of clorsulon.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 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 part 556 is amended as follows:

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

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

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.163 is revised to read as follows:

§ 556.163 Clorsulon.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of clorsulon is 8 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Kidney (the target tissue).* The tolerance for parent clorsulon (the marker residue) is 1.0 part per million.

(ii) *Muscle.* The tolerance for parent clorsulon (the marker residue) is 0.1 part per million.

(2) [Reserved]

Dated: June 25, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 01-16990 Filed 7-5-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09-01-054]

RIN 2115-AA97

Safety Zone; Menominee Waterfront Festival 2001, Menominee, Michigan

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone by the Menominee municipal marina for the Menominee Waterfront Festival 2001 fireworks display. This safety zone is necessary to protect spectators and vessels from the hazards associated with the storage, preparation, and launching of fireworks. This safety zone is intended to restrict vessel traffic from a portion of the Menominee municipal marina, Menominee, Michigan.

DATES: This temporary rule is effective from 9:20 p.m. until 10:10 p.m. (CST) on August 4, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD09-01-054] and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207 between 7 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Timothy Sickler, Port Operations Chief, Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207. The phone number is (414) 747-7155.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The permit application did not allow sufficient time for the publication of an NPRM followed by a temporary final rule effective 30 days after publication. Any delay of the effective date of this rule would be contrary to the public interest by exposing the public to the known dangers associated with fireworks displays and the possible loss of life, injury, and damage to property.