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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.

Background and Purpose

This safety zone is established to safeguard the public from the hazards associated with the launching of fireworks by the Menominee municipal marina, Menominee, Michigan. The size of the zone was determined by using previous experiences with fireworks displays in the Captain of the Port Milwaukee zone and local knowledge about wind, waves, and currents in this particular area.

The safety zone will be in effect on August 4, 2001, from 9:20 p.m. through 10:10 p.m. (CST). The safety zone encompasses all waters bounded by the arc of a circle with a 840-foot radius with its center in approximate position 45° 20.05' N, 087° 36.49' W, offshore of Menominee municipal marina, Menominee, Michigan. The size of the zone was determined using the National Fire Prevention Association guidelines and local knowledge concerning wind, waves, and currents.

All persons and vessels shall comply with the instructions of the Captain of the Port Milwaukee or his designated on scene patrol personnel. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Milwaukee or his designated on scene representative. The Captain of the Port Milwaukee may be contacted via VHF Channel 16.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it 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).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities: the owners or operators of vessels intending to transit or anchor in the vicinity of Menominee municipal marina from 9:20 p.m. until 10:10 p.m. (CST) on August 4, 2001.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be in effect for only 50 minutes on one day and late in the day when vessel traffic is minimal. Vessel traffic may enter or transit through the safety zone with the permission of the Captain of the Port Milwaukee or his designated on scene representative. Before the effective period, we will issue maritime advisories widely available to users of the Menominee municipal marina.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Milwaukee (See ADDRESSES.)

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An

unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

The Coast Guard considered the environmental impact of this rule and

concluded that under figure 2-1, paragraph (34)(g), of Commandant Instruction M16475.IC, this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05-1(g), 6.04-1, 6.04-6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09-916 is added to read as follows:

§ 165.T09-916 Safety Zone: Menominee Municipal Marina, Menominee, Michigan.

(a) *Location.* The safety zone encompasses all waters bounded by the arc of a circle with a 840-foot radius with its center in approximate position 45°20.05' N, 087°36.49' W, located approximately 840 feet offshore Menominee municipal marina, Menominee, Michigan.

(b) *Effective times and dates.* From 9:20 p.m. until 10:10 p.m. on August 4, 2001.

(c) *Regulations.* (1) The general regulations contained in § 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port Milwaukee or the designated on scene patrol personnel. Coast Guard patrol personnel include commissioned, warrant or petty officers of the U.S. Coast Guard. Upon being hailed by a U.S. Coast Guard vessel via siren, radio, flashing light, or other means, the operator shall proceed as directed. This safety zone should not adversely effect shipping. However, commercial vessels may request permission from the Captain of the Port Milwaukee to enter or transit the safety zone. Approval will be made on a case-by-case basis. Requests must be in advance and approved by the Captain of the Port Milwaukee before transits will be authorized. The Captain of the Port Milwaukee may be contacted via U.S. Coast Guard Group Milwaukee on Channel 16, VHF-FM.

Dated: June 26, 2001.

B.R. Emond,

Lieutenant Commander, U.S. Coast Guard, Acting Captain of the Port, Milwaukee, Wisconsin.

[FR Doc. 01-16968 Filed 7-5-01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD112-3066a; FRL-7008-6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule to approve reasonable available control technology (RACT) to limit volatile organic compound (VOC) emissions from distilled spirits facilities. In the direct final rule published on May 22, 2001 (66 FR 28058), we stated that if we received adverse comment by June 21, 2001, the rule would be withdrawn and not take effect. EPA received adverse comments on June 21, 2001. EPA will address the comments received in a subsequent final action based upon the proposed action also published on May 22, 2001 (66 FR 28138). EPA will not institute a second comment period on this action.

DATES: The Direct final rule published at 66 FR 28058, May 22, 2001, is withdrawn as of July 6, 2001.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, Air Quality Planning & Information Services Branch, Mailcode 3AP21, US Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Phone (215) 814-2182.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Dated: June 27, 2001.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

Accordingly, the direct final rule adding 40 CFR 52.1070(c)(160) is withdrawn as of July 6, 2001.

[FR Doc. 01-16950 Filed 7-5-01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[SC-038-200102(c); FRL-7008-8]

Withdrawal of Direct Final Rule for Approval and Promulgation of State Plans for Designated Facilities and Pollutants: South Carolina

AGENCY: Environmental Protection Agency.

ACTION: Withdrawal of direct final rule.

SUMMARY: The United States Environmental Protection Agency (EPA) is withdrawing the direct final rule approving the section 111(d)/129 Plan submitted by the South Carolina Department of Health and Environmental Control (DHEC). The direct final rule was published in the **Federal Register** on May 7, 2001 (66 FR 22927).

DATES: The direct final rule published at 66 FR 22927, May 7, 2001, is withdrawn as of July 6, 2001.

FOR FURTHER INFORMATION CONTACT: Gregory Crawford at EPA Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303-3104, (404) 562-9046.

SUPPLEMENTARY INFORMATION: On May 7, 2001 (66 FR 22970), EPA proposed to approve the section 111(d)/129 Plan for the State of South Carolina submitted on September 19, 2000, for implementing and enforcing the Emission Guidelines applicable to existing Hospital /Medical/ Infectious Waste Incinerators. On the same day (66 FR 22927), EPA also published a direct final rule approving the State Plan. The action provided a 30-day public comment period and explained that if we received adverse comments, we would withdraw the relevant direct final action.

We received comments and are therefore withdrawing the direct final rule approving the State Plan. We are not opening an additional comment period. We intend to finalize action on these rules based on the May 7, 2001 proposed action.

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Hospital/medical/infectious waste incineration, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 22, 2001.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 01-16954 Filed 7-5-01; 8:45 am]

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