

**ACTION:** Final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of April 27, 2010, for the final rule that appeared in the **Federal Register** of March 26, 2010. The final rule amended the color additive regulations by increasing the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp.

**DATES:** The effective date for the final rule published in the **Federal Register** of March 26, 2010 (75 FR 14491) is confirmed as April 27, 2010.

**FOR FURTHER INFORMATION CONTACT:** Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1264.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 26, 2010 (75 FR 14491), FDA amended the color additive regulations in § 73.2110 (21 CFR 73.2110) by increasing the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp.

FDA gave interested persons until April 26, 2010, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of March 26, 2010, should be confirmed.

#### List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, notice is given that no objections or requests for a hearing were filed in response to the March 26, 2010, final rule. Accordingly, the amendments issued thereby became effective April 27, 2010.

Dated: June 11, 2010.

**Mitchell A. Cheeseman,**

*Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*

[FR Doc. 2010-14598 Filed 6-16-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

[Docket No. FDA-2010-N-0002]

#### New Animal Drugs for Use in Animal Feeds; Florfenicol

**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 Intervet, Inc. The supplemental NADA provides for the manufacture of florfenicol Type B medicated swine feeds.

**DATES:** This rule is effective June 17, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, email: [cindy.burnsteel@fda.hhs.gov](mailto:cindy.burnsteel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed a supplement to NADA 141-264 for use of NUFLOL (florfenicol) Antibiotic Type A Medicated Article for Swine by veterinary feed directive that provides for the manufacture of Type B medicated swine feeds. The supplemental NADA is approved as of May 13, 2010, and the regulations are amended in 21 CFR 558.4 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

#### § 558.4 [Amended]

■ 2. In paragraph (d) of § 558.4, in the "Category II" table, in the "Type B maximum (100x)" column, in the entry for "Florfenicol", remove "Swine feed: n/a" and in its place add "Swine feed: 9.1 g/lb (2.0%)".

Dated: June 14, 2010.

**Elizabeth Rettie,**

*Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 2010-14611 Filed 6-16-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[USCG-2010-0446]

#### Safety Zone, Milwaukee Harbor, Milwaukee, WI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the Milwaukee Harbor safety zone during eight separate periods between 10 p.m. on July 15, 2010 through 10 p.m. on July 25, 2010. This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after fireworks events. This rule will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after fireworks events. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port, Sector Lake Michigan.

**DATES:** The regulations in 33 CFR 165.935 will be enforced during eight separate periods between from 10 p.m. on July 15, 2010 through 10 p.m. on July 25, 2010.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call

or e-mail BM1 Adam Kraft, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747-7154, e-mail [Adam.D.Kraft@uscg.mil](mailto:Adam.D.Kraft@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the safety zone listed in 33 CFR 165.935, Safety Zone, Milwaukee Harbor, Milwaukee, WI, for the following events:

(1) *Festa Italiana fireworks display*; on July 15, 2010 from 10 p.m. through 10:45 p.m.

(2) *Festa Italiana fireworks display*; on July 16, 2010 from 10 p.m. through 10:45 p.m.

(3) *Festa Italiana fireworks display*; on July 17, 2010 from 10 p.m. through 10:45 p.m.

(4) *Festa Italiana fireworks display*; on July 18, 2010 from 10 p.m. through 10:45 p.m.

(5) *German Festival fireworks display*; on July 22, 2010 from 10:15 p.m. through 11 p.m.

(6) *German Festival fireworks display*; on July 23, 2010 from 10:15 p.m. through 11 p.m.

(7) *German Festival fireworks display*; on July 24, 2010 from 10:15 p.m. through 11 p.m.

(8) *German Festival fireworks display*; on July 25, 2010 from 9:15 p.m. through 10 p.m.

All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her designated on-scene representative to enter, move within or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or his or her designated on-scene representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.935 Safety Zone, Milwaukee Harbor, Milwaukee, WI and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via Broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port, Sector Lake Michigan, will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone.

The Captain of the Port, Sector Lake Michigan, or his or her designated on-

scene representative may be contacted via VHF-FM Channel 16.

Dated: June 2, 2010.

**L. Barndt,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.*

[FR Doc. 2010-14584 Filed 6-16-10; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2010-0452]

RIN 1625-AA00

#### Safety Zone; Festivals & Fireworks Celebration, East Moran Bay, Lake Huron, St. Ignace, MI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on East Moran Bay, Lake Huron, St. Ignace, MI. This zone is intended to restrict vessels from a portion of Lake Huron during the Festivals & Fireworks Celebration fireworks display taking place on ten separate occasions from June 26, 2010 through September 5, 2010. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays.

**DATES:** This rule is effective from 9 p.m. on June 26, 2010 until 11 p.m. on September 5, 2010.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0452 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0452 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or e-mail BMC Gregory Ford, Marine Event Coordinator, U.S. Coast Guard Sector Sault Sainte Marie; telephone 906-635-3222, e-mail [Gregory.C.Ford@uscg.mil](mailto:Gregory.C.Ford@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

## SUPPLEMENTARY INFORMATION:

### Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is contrary to the public interest to delay the effective date of this rule. Delaying the effective date by first publishing an NPRM would be contrary to the safety zone's intended objective since immediate action is needed to protect person's and vessels against the hazards associated with fireworks displays on navigable waters. Such hazards include premature detonations, dangerous detonations, dangerous projectiles and falling or burning debris. Additionally, the zone should have negligible impact on vessel transits due to the fact that vessels will be limited from the area for only two hours on the specified dates and vessels can still transit in the majority of East Moran Bay during the event. Accordingly, under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property.

### Basis and Purpose

This temporary safety zone is necessary to ensure the safety of vessels and spectators from hazards associated with a fireworks display. Based on the explosive hazards of fireworks, the Captain of the Port Sault Sainte Marie has determined that fireworks launches proximate to watercraft pose significant risk to public safety and property. The likely combination of large numbers of recreation vessels, congested waterways, darkness punctuated by bright flashes of light, alcohol use, and debris falling into the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement