# Rules and Regulations

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 558

### 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 the approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the use of florfenicol by veterinary feed directive (VFD) for the control of mortality in freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida*.

**DATES:** This rule is effective November 26, 2007.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 141–246 that provides for use of AQUAFLOR (florfenicol), a Type A medicated article, by VFD to formulate Type C medicated feed for the control of mortality in freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida*. The supplemental application is approved as of October 26, 2007, and the regulations are amended in 21 CFR 558.261 to reflect the approval and a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc–2), this supplemental approval qualifies for 7 years of exclusive marketing rights beginning on the date of approval because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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.

■ 2. In § 558.261, revise paragraph (e) to read as follows:

**§ 558.261 Florfenicol.**

* * * * *

(e) *Conditions of use*—

(1) *Swine*—

| Florfenicol in grams/ton of feed | Indications for use | Limitations |
|---|---|---|
| 182 | For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD. | Feed continuously as a sole ration for 5 consecutive days. The safety of florfenicol on swine reproductive performance, pregnancy, and lactation have not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter. |

(2) *Fish*—

| Florfenicol in grams/ ton of feed | Indications for use | Limitations |
|---|---|---|
| (i) 182 to 1,816 | Catfish: For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*. | Feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/ lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 12 days prior to slaughter. |
| (ii) 182 to 1,816 | Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*. | Feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter. |

Dated: November 9, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7–22942 Filed 11–23–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

**[CGD01–07–157]**

**RIN 1625–AA00**

## Safety Zone: Ambrose Light, Offshore Sandy Hook, NJ, Atlantic Ocean

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone in the waters of the Atlantic Ocean within a 250 yard radius of Ambrose Light (LLNR 720) located at position 40°27′00″ N, 073°48′00″ W, approximately 8.35 nautical miles east of Sandy Hook, NJ. This safety zone is necessary to provide for the safety of life, property and the environment on navigable waters of the United States during survey and reconstruction of the Ambrose Light that was recently damaged. This safety zone is intended to keep vessels a safe distance from Ambrose Light during the survey and reconstruction operations.

**DATES:** This rule is effective from 12:01 a.m. on November 5, 2007 through 11:59 p.m. on May 5, 2008.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket CGD01–07–157 and are available for inspection or copying at Coast Guard Sector New York, Room 209, Staten Island, New York 10305 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander Mike McBrady, Waterways Management Division, Coast Guard Sector New York (718) 354–2353.

**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. A notice and comment period was not held for this rulemaking because the safety zone is needed in response to an emergency situation created when the Ambrose Light was struck and damaged by a vessel. A survey and repairs are needed immediately in order to restore the light to normal operations. Delaying the necessary survey and repairs in order to conduct a notice and comment period would be contrary to the public interest.

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** as immediate action is needed to protect vessels transiting the area from the hazards of the damaged light tower and from the hazards associated with survey and reconstruction operations. Any delay in implementing this rule would be contrary to public interest since immediate action is needed due to the potential hazards associated with the unstable light, the possibility of it collapsing, or a vessel grounding on the remains of Ambrose Light (LLNR 720).

### Background and Purpose

On Saturday, November 3, 2007, the M/T AXEL SPIRIT allided with Ambrose Light (LLNR 720) in position 40°27′00″ N, 073°48′00″ W approximately 8.35 nautical miles east of Sandy Hook, NJ. Initial damage assessment indicates that the Ambrose Light is no longer watching properly and in danger of collapse, creating an additional hazard to vessels operating in the area. This safety zone is being created in response to this emergency situation in order to keep mariners away from the hazards associated with the damaged structure and from the hazards associated with survey and reconstruction operations.

### Discussion of Rule

This rule will provide for the safety of vessel traffic in and around Ambrose Light (LLNR 720). This regulation establishes a temporary safety zone on the navigable waters of the Atlantic Ocean within a 250-yard radius of position 40°27′00″ N, 073°48′00″ W, approximately 8.35 nautical miles east of Sandy Hook, NJ. The rule described herein prohibits the transit of vessels through the safety zone unless specifically authorized by the Captain of the Port, New York. This safety zone is in effect from 12:01 a.m. on November 5, 2007 until 11:59 p.m. on May 5, 2008. The zone will be enforced during the entire effective period unless the survey and reconstruction work is completed prior to the last effective date. If survey and reconstruction is completed before May 5, 2008, the Coast Guard will cease enforcement of the safety zone.