

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

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Certifier L. CAWSON  
DDM

**New Animal Drugs For Use in Animal Feeds; Florfenicol**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 [*insert date of publication in the Federal Register*].

**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](mailto: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 AQUAFLO (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.**

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(e) \* \* \* Conditions of use --  
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IPC per OFR  
(Jim Wickliffe)  
11-21-07

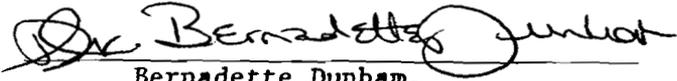
(1) Swine—

Florfenicol in grams/ton of feed	Indications for use	Limitations
182	For the control of swine respiratory disease (SRD) associated with <i>Actinobacillus pleuropneumoniae</i> , <i>Pasteurella multocida</i> , <i>Streptococcus suis</i> , and <i>Bordetella bronchiseptica</i> 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 <i>Edwardsiella ictaluri</i> .	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 <i>Flavobacterium psychrophilum</i> and furunculosis associated with <i>Aeromonas salmonicida</i> .	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: 11/09/07  
November 9, 2007.



Bernadette Dunham,  
Deputy Director,  
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11-19-07

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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