DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs; 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 coldwater disease associated with *Flavobacterium psychrophilum*.

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.*

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 coldwater disease associated with *F. psychrophilum*. The supplemental application is approved as of March 19, 2007, and the regulations are amended in 21 CFR 556.283, 558.4, and 558.261 to reflect the approval.

CV06100 2007-141-246

NFR2

The single VFD order form for florfenicol includes both catfish and freshwater-reared salmonid indications because each comprises multiple species and is approved in each for use under similar directions and conditions of use.

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 March 19, 2007, 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

21 CFR Part 556

Animal drugs, Foods.

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 parts 556 and 558 are 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. In § 556.283, add paragraph (b)(4) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) * * *

(4) *Salmonids.* The tolerance for florfenicol amine (the marker residue) in muscle/skin (the target tissues) is 1 ppm.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 4. In paragraph (d) of § 558.4, in the "Category II" table, revise the entry in alphabetical order for "Florfenicol" to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent[1] Type A	Type B maximum (100x)	Assay limits percent[1] Type B/C[2]
• • •	•	• •	•
Florfenicol	90–110	Swine feed: n/a Catfish feed: n/a Salmonid feed: n/a	Swine feed: 85–115 Catfish feed: 80–110 Salmonid feed: 80–110
• • •	•	• •	•

[1]Percent of labeled amount.
[2]Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

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■ 5. In § 558.261, revise paragraph (a)(2), paragraph (c)(2)(i), and the first two sentences of paragraph (e)(2)(iii); and add new paragraph (e)(3) to read as follows:

§ 558.261 Florfenicol.

(a) * * *

(2) 500 grams per kilogram for use as in paragraphs (e)(2) and (e)(3) of this section.

* * * * *

(c) * * *

(2) * * *

(i) For catfish and freshwater-reared salmonids, must not exceed 15 days from the date of issuance;

* * * * *

(e) * * *

(2) * * *

(iii) * * * 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. * * *

(3) *Freshwater-reared salmonids*—(i) *Amount.* 10 milligrams florfenicol per kilogram of fish daily for 10 consecutive days.

(ii) *Indications for use.* For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum.*

(iii) *Limitations.* 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: April 9, 2007

April 9, 2007.

Bernadette Dunham, DVM, Ph.D.

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