DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for the use of florfenicol by veterinary feed directive in catfish feed for the control of mortality due to enteric septicemia of catfish.

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., 1095 Morris Ave., Union, NJ 07083, filed NADA 141–246 that provides for use of AQUAFLOR (florfenicol) Type A medicated article by veterinary feed directive to formulate Type C medicated feeds for the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri.* The NADA is approved as of October 24, 2005, and the regulations are amended in 21 CFR 556.283 and in part 558 (21 CFR part 558) by revising § 558.4 and by adding new § 558.261 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

NFR 1

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 approval qualifies for 7 years of exclusive marketing rights beginning October 24, 2005, 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. Add paragraphs (b)(3) and (c) in § 556.283 to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) * * *

(3) *Catfish.* The tolerance for florfenicol amine (the marker residue) in muscle (the target tissue) is 1 ppm.

(c) *Related conditions of use.* See §§ 520.955, 522.955, and 558.261 of this chapter.

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, add an 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	n/a	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 Type C medicated feed.

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■ 5. Add § 558.261 to read as follows:

§ 558.261 Florfenicol.

(a) *Specifications.* Type A medicated article containing 500 grams florfenicol per kilogram.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law limits this drug to use under the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements.

(2) The expiration date of veterinary feed directives (VFDs) for florfenicol must not exceed 15 days from the date of issuance. VFDs for florfenicol shall not be refilled.

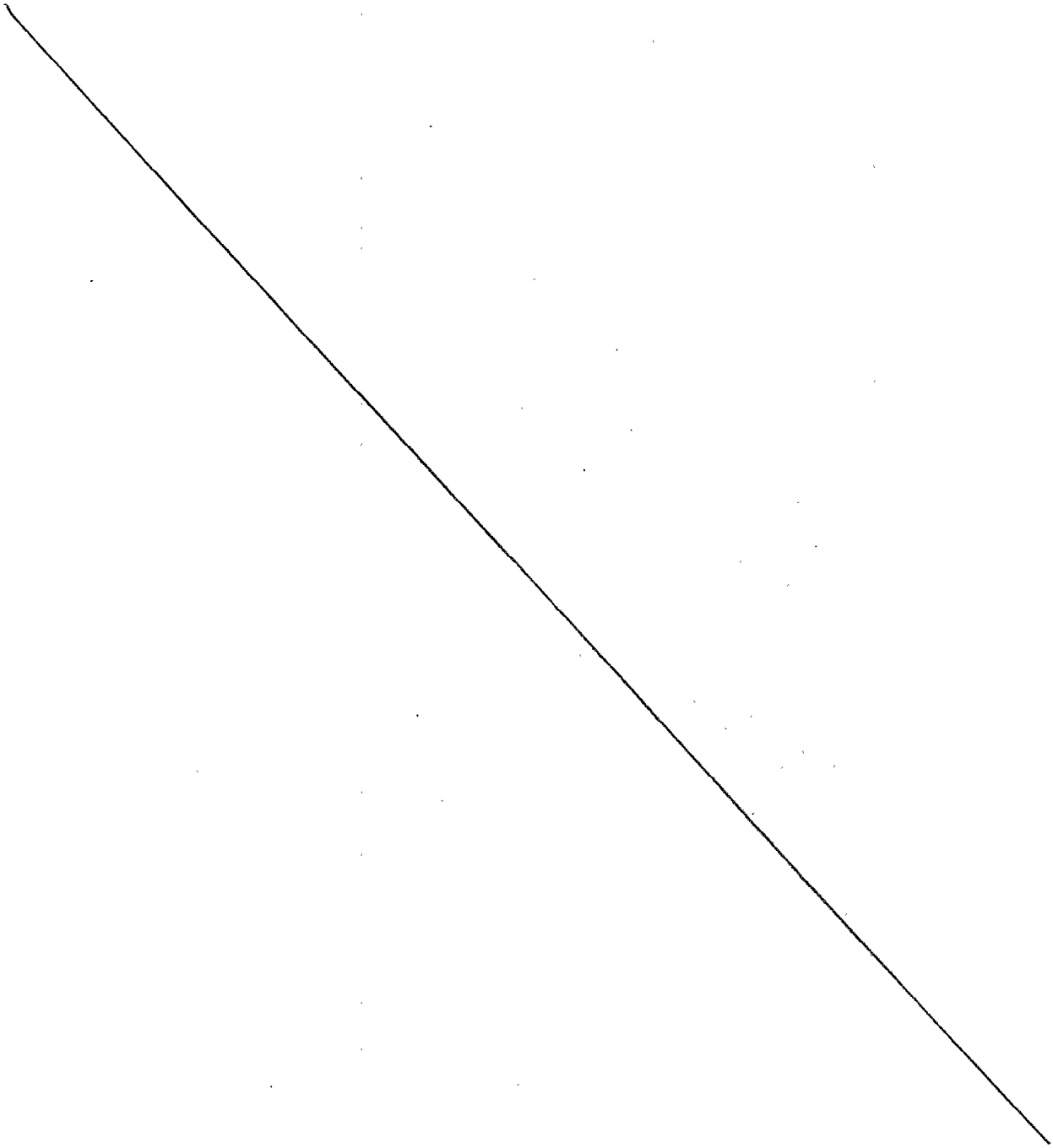
(d) *Related tolerances.* See § 556.283 of this chapter.

(e) *Conditions of use*—(1) *Catfish*—(i) *Amount.* 10 milligrams per kilogram of fish daily for 10 consecutive days.

(ii) *Indications for use.* For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri.*

(iii) *Limitations.* Feed containing florfenicol shall not be fed to catfish for more than 10 days. Following 10 days administration, fish should be re-

evaluated by a licensed veterinarian before reinitiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for the 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.

(2) [Reserved]

Dated: 11/8/05
November 8, 2005.

Andrew J. Beaulieu,
Acting Director,
Center for Veterinary Medicine,

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