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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 516 and 556

Display Date 10-5-07
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Certifier A. Corbin

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 conditional approval of an application for conditional approval of a new animal drug intended for a minor species filed by Schering-Plough Animal Health Corp. The application seeks conditional approval of the use of florfenicol by veterinary feed directive for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*.

DATES: This rule is effective October 9, 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.hhs.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed an application for conditional approval (141-259) that provides for the use of AQUAFLO-CA1 (florfenicol), a Type A medicated article, by veterinary feed directive to formulate Type C medicated feed for the control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare*. In accordance with the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Minor Use and

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Minor Species Animal Health Act of 2004 (MUMS Act), this drug is conditionally approved as of April 13, 2007, and the regulations are amended by adding 21 CFR 516.1215 and by revising 21 CFR 556.283 to reflect the conditional approval of this application. The effect of this final rule is delayed until October 9, 2007, pending establishment of part 516 (72 FR 41010, July 26, 2007).

In accordance with the freedom of information provisions of 21 CFR part 20, a summary of safety and effectiveness data and information submitted to support conditional approval of this application for conditional approval 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.

AQUAFLOL-CA1 in the dosage form and for the intended uses conditionally approved by FDA under application number 141-259 qualifies for 7 years of exclusive marketing rights beginning on the date of approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the act (21 U.S.C. 360ccc-2(c)) because it has been declared a designated new animal drug by FDA under section 573(a) of the act.

FDA has determined under 21 CFR 25.33(d)(4) 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

Administrative practice and procedure; Animal drugs, Confidential business information,
 21 CFR Part 516 Reporting and recordkeeping requirements.

~~New Animal Drugs For Minor Use and Minor Species~~

3DC per OFR
 - Kent files

21 CFR Part 556

10/4/07

Animal drugs, Foods.

■ 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 516 ^{s and 556 are} amended as follows:

3DC per OFR
 - Kent files

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

10/4/07

■ 1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-2, 371.

■ 2. Add subpart E to read as follows:

Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

§ 516.1215 Florfenicol.

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

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

(c) *Special considerations.* Labeling shall bear the following:

“Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-259. Extra-label use of this drug in or on animal feed is strictly prohibited.”

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

(e) *Conditions of use*—(1) *Catfish*—(i) *Amount*. Feed 182 to 1816 g florfenicol per ton of feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish.

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

(iii) *Limitations*. Feed containing florfenicol shall not be fed to catfish 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. Federal law limits this drug to use under the professional supervision of a licensed veterinarian. The expiration date of veterinary feed directives (VFDs) for florfenicol must not exceed 15 days from the date of prescribing. VFDs for florfenicol shall not be refilled. See § 558.6 of this chapter for additional requirements.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. In § 556.283, revise paragraph (c) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(c) *Related conditions of use.* See §§ 516.1215, 520.955, 522.955, and 558.261 of this chapter.

Dated: 9/27/07
September 27, 2007.

Bernadette Dunham 9/27/07
Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.

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

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

A handwritten signature in black ink, appearing to be "H. R. ...", written over a horizontal line.