

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 520 and 556

1 2 6 6 '02 DEC 23 P12 57

Oral Dosage Form 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 use of a florfenicol concentrate solution to make medicated drinking water for administration to swine for the treatment of respiratory disease. FDA is also amending the regulations to add tolerances for residues of florfenicol in edible tissues of swine.

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: jgotthar@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 141-206 for NUFLOR (florfenicol) 2.3% Concentrate Solution used to make medicated drinking water for administration to swine for the treatment of respiratory disease associated with several bacterial pathogens. The NADA is approved as of September 4, 2002, and the regulations are amended in 21 CFR part 520 by adding § 520.955 to

reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulations are amended in 21 CFR 556.283 to establish tolerances for residues of florfenicol in edible tissues of treated swine and to reflect a current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 4, 2002.

The agency has determined under 21 CFR 25.33(d)(5) 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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

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 parts 520 and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.955 is added to read as follows:

§ 520.955 Florfenicol.

(a) *Specifications.* Each milliliter (mL) contains 23 milligrams (mg) florfenicol.

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

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

(d) *Conditions of use in swine—(1) Amount.* Administer in drinking water *ad libitum* at 400 mg per gallon (100 parts per million (ppm)) for 5 consecutive days.

(2) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis* and *Streptococcus suis* Type 2.

(3) *Limitations.* Do not slaughter within 16 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**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. Section 556.283 is amended by revising paragraph (b) to read as follows:

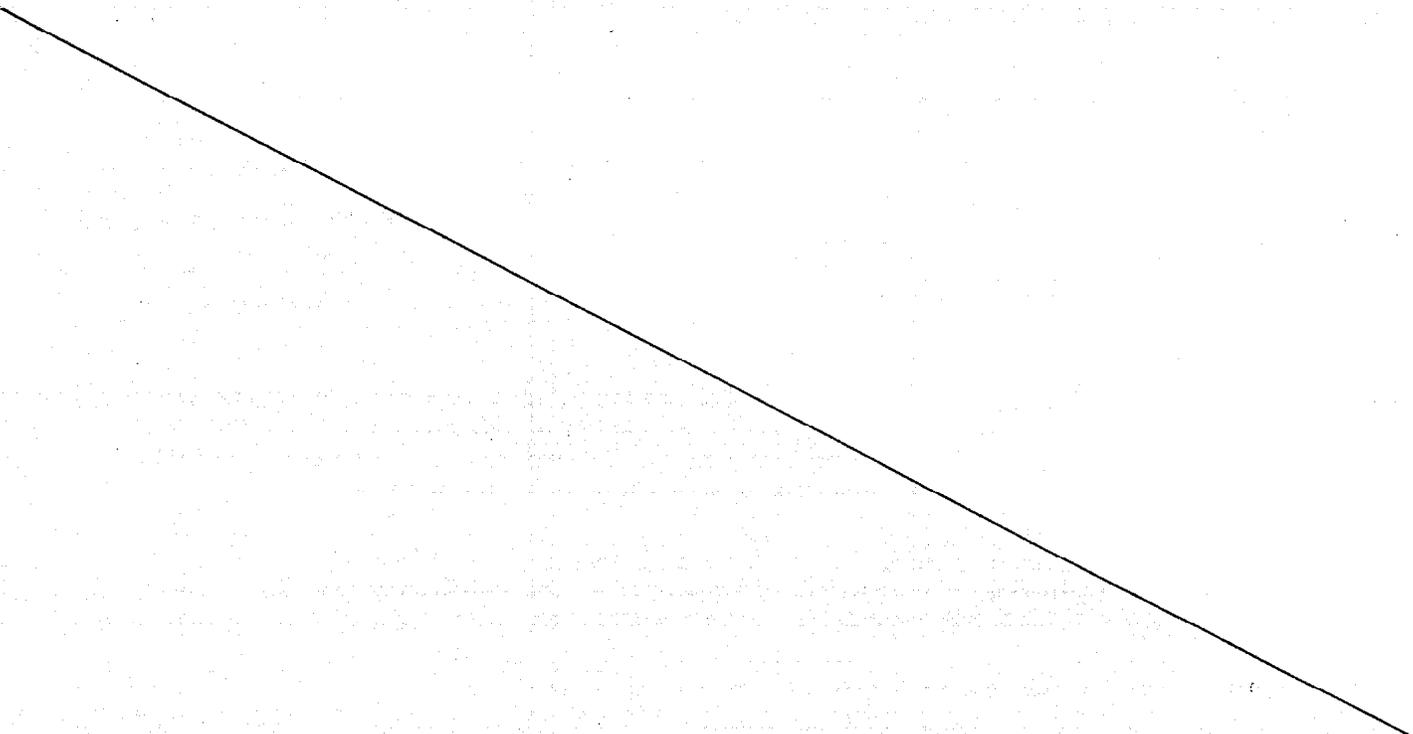
§ 556.283 Florfenicol.

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(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for florfenicol amine (the marker residue) is 3.7 parts per million (ppm).

(ii) *Muscle*. The tolerance for florfenicol amine (the marker residue) is 0.3 ppm.

(2) *Swine*—(i) *Liver (the target tissue)*. The tolerance for parent florfenicol (the marker residue) is 2.5 ppm.

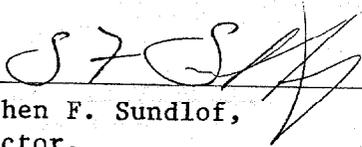


(ii) *Muscle*. The tolerance for parent florfenicol (the marker residue) is 0.2

ppm.

Dated: 12/13/02

December 13, 2002.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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