

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier L. CLAWSON
DDM

Implantation or Injectable Dosage Form New Animal Drugs; Gentamicin

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 an abbreviated new animal drug application (ANADA) filed by Sparhawk Laboratories, Inc. The ANADA provides for use of a gentamicin sulfate injectable solution in piglets for treatment of porcine colibacillosis.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, filed ANADA 200-394 for the use of Gentamicin Sulfate Injection in piglets up to 3 days old for treatment of porcine colibacillosis caused by strains of *Escherichia coli* sensitive to gentamicin. Sparhawk Laboratories, Inc.'s Gentamicin Sulfate Injection is approved as a generic copy of Schering-Plough Animal Health Corp.'s GARACIN Piglet Injection, approved under NADA 103-037. The ANADA is approved as of November 17, 2006, and the regulations in 21 CFR 522.1044 are amended to

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reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

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.

FDA has determined under 21 CFR 25.33(a)(1) 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 in 21 CFR Part 522

Animal drugs.

■ 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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. In § 522.1044, revise the section heading and paragraphs (a) and (b) to read as follows:

§ 522.1044 Gentamicin.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 5, 50, or 100 milligrams (mg) gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000061 for use of 5 mg per milliliter (/mL) solution in swine as in paragraph (d)(4), 50 mg/mL solution in dogs and cats as in paragraph (d)(1), 50 mg/mL and 100 mg/mL solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

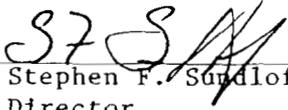
(2) No. 058005 for use of 5 mg/mL solution in swine as in paragraph (d)(4) of this section.

(3) No. 000010 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) No. 059130 for use of 100 mg/mL solution in turkeys as in paragraph (d)(2) and in chickens as in paragraph (d)(3) of this section.

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Dated: 12/13/06
December 13, 2006.



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

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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