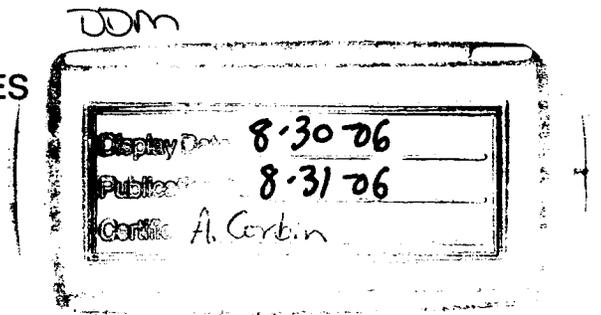


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529



**Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate  
Intrauterine Solution**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 generic gentamicin sulfate solution as an intrauterine infusion for the control of bacterial metritis and as an aid in improving conception in mares.

**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](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, filed ANADA 200-395 for the use of Gentamicin Sulfate Solution for the control of bacterial infections of the uterus (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin. Sparhawk Laboratories, Inc.'s gentamicin sulfate solution is approved as a generic copy of Schering-Plough Animal Health Corp.'s GENTOCIN (gentamicin sulfate) solution veterinary, approved

ANADA 2006-200-395  
CV0659

NFL2

under NADA 46-724. The ANADA is approved as of July 31, 2006, and the regulations in 21 CFR 529.1044a are amended to 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 529**

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 529 is amended as follows:

#### **PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. Revise § 529.1044a to read as follows:

**§ 529.1044a     Gentamicin sulfate intrauterine solution.**

(a) *Specifications.* Each milliliter of solution contains 50 or 100 milligrams gentamicin sulfate.

(b) *Sponsors.* See Nos. 000010, 000061, 000856, 057561, 058005, 059130, and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Infuse 2 to 2.5 grams per day for 3 to 5 days during estrus.

(2) *Indications for use.* For control of bacterial infections of the uterus (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

(3) *Limitations.* Do not use in horses intended for human consumption.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 8/11/06  
August 11, 2006.

S F Sundlof

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

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

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