



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2011-N-0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin and Betamethasone Spray

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the original approval of an abbreviated new animal drug application (ANADA) filed by Sparhawk Laboratories, Inc. The ANADA provides for the veterinary prescription use of gentamicin sulfate and betamethasone valerate topical spray in dogs.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, filed ANADA 200-416 that provides for veterinary prescription use of Gentamicin Topical Spray (gentamicin sulfate and betamethasone valerate) in dogs. Sparhawk Laboratories, Inc.'s Gentamicin Topical Spray is approved as a generic copy of Intervet, Inc.'s GENTOCIN Topical Spray, approved under NADA 132-338. The ANADA is approved as of November 10, 2011, and the regulations are amended in 21 CFR 524.1044f to reflect the approval and revised terminology in the indication.

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.

The Agency has determined under 21 CFR 25.33 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 524

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 524 is amended as follows:

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1044f [Amended]

2. In § 524.1044f, revise paragraphs (b) and (c)(2) to read as follows:

§ 524.1044f Gentamicin and betamethasone spray.

* * * * *

(b) Sponsors. See Nos. 000061, 054925, 058005, 058829, and 065531 in § 510.600(c) of this chapter.

(c) * * *

(2) Indications for use. For the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.

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Dated: January 19, 2012.

William T. Flynn,
Acting Director,
Center for Veterinary Medicine.