

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524



Display Date 2-7-07  
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Certifier [Signature]

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

**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 First Priority, Inc. The ANADA provides for topical use of a gentamicin sulfate and betamethasone valerate topical spray on dogs for the treatment of infected superficial lesions.

**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:** First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-415 for Gentamicin Sulfate Topical Spray (gentamicin sulfate, USP with betamethasone valerate, USP) for use on dogs for the treatment of infected superficial lesions caused by bacteria sensitive to gentamicin. First Priority's Gentamicin Sulfate Topical Spray is approved as a generic copy of Schering-Plough Animal Health Corp.'s GENTOCIN Topical Spray, approved under NADA 132-338. The ANADA is approved as of January 12, 2006, and 21 CFR 524.1044f is amended to reflect the approval

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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.

The agency 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 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**

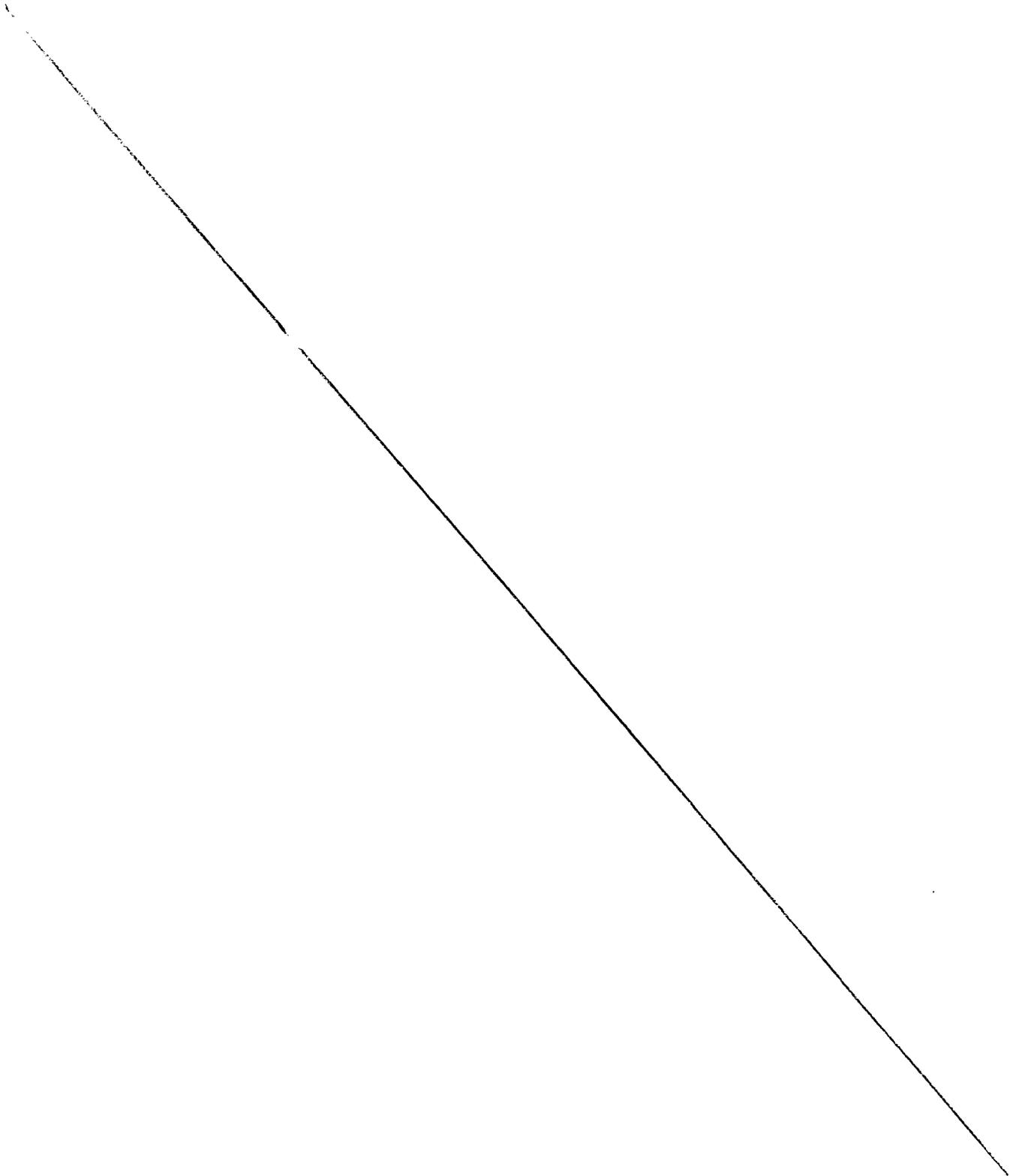
■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. In § 524.1044f, revise the section heading and paragraph (b) to read as follows:

**§ 524.1044f      Gentamicin and betamethasone spray.**

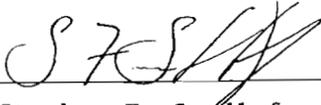
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(b) See Nos. 000061, 054925, and 058829 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: 1/29/07  
January 29, 2007.



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

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



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