

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

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Compiler	D. Hawkins

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment

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 Altana Inc. The ANADA provides for veterinary prescription use of gentamicin sulfate, betamethasone valerate, clotrimazole ointment for the treatment of canine otitis externa.

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

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: daniel.benz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Altana Inc., 60 Baylis Rd., Melville, NY 11747, filed ANADA 200-283 that provides for veterinary prescription use of VETRO-MAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP, ointment) for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin. Altana Inc.'s VETRO-MAX Otic Ointment is approved as a generic copy of Schering-Plough Animal Health Corp.'s OTOMAX Ointment approved under NADA 140-896. The ANADA is approved

as of June 1, 2006, and the regulations are amended in 21 CFR 524.1044g to reflect the approval. 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 § 524.1044g, add paragraph (b)(4) to read as follows:

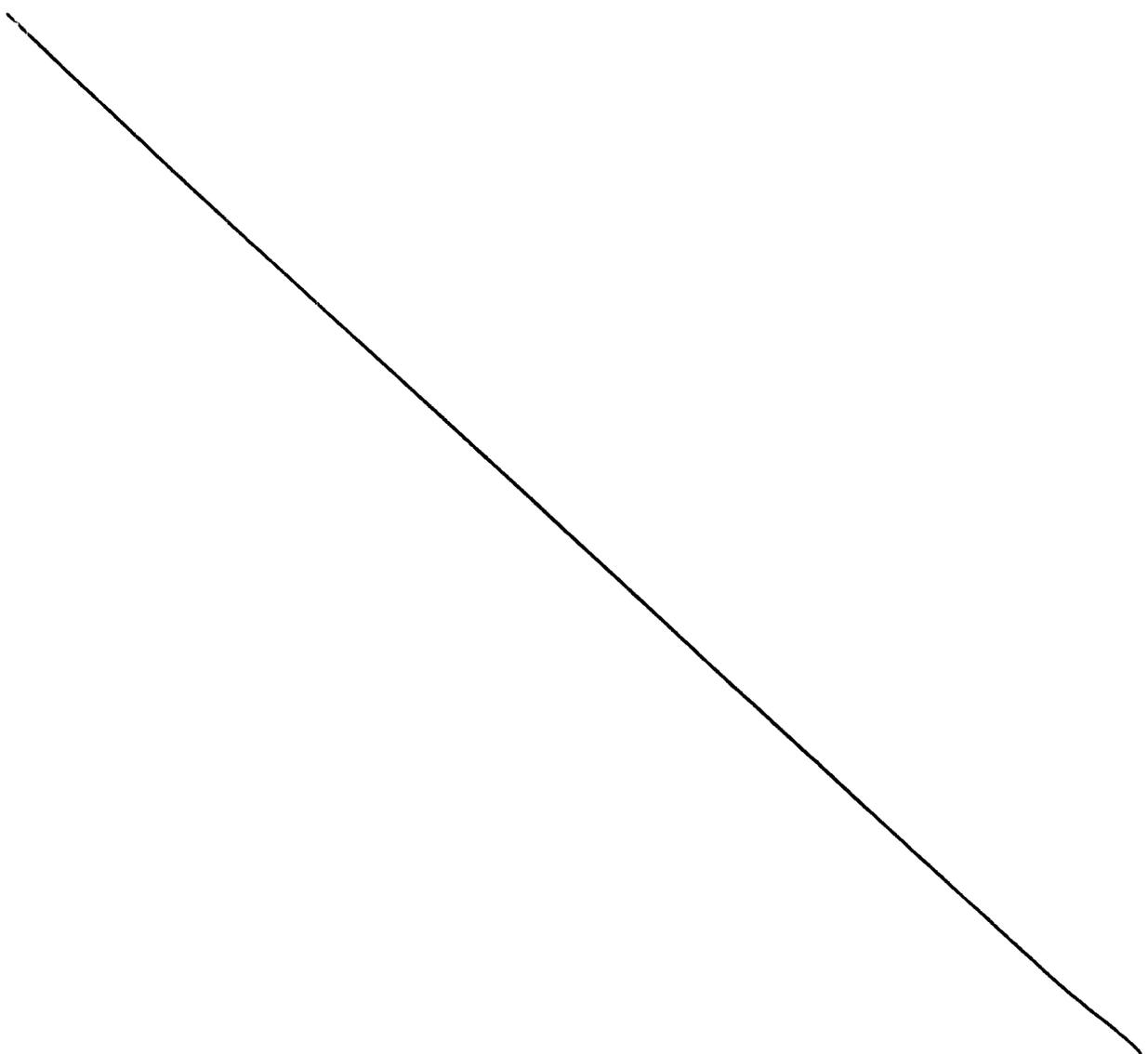
§ 524.1044g **Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.**

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(b) * * *

(4) No. 025463 for use of 7.5- or 15-g tubes, or 215-g bottles.

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Dated: 6/22/06
June 22, 2006.

cv0614

SF Sundlof

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

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

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Dawn P. Hawkins