

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

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Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Mometasone Furoate, Clotrimazole Otic Suspension; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for a new container size, a 7.5-gram dropper bottle, from which gentamicin sulfate, mometasone furoate, clotrimazole otic suspension may be administered for the treatment of otitis externa in dogs. The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

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

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 141-177 for use of MOMETAMAX (gentamicin sulfate, U.S.P.; mometasone furoate

monohydrate; and clotrimazole, U.S.P.) Otic Suspension for the treatment of otitis externa in dogs. The supplement provides for a new container size, a 7.5-gram dropper bottle. The supplemental NADA is approved as of June 1, 2005, and the regulations are amended in 21 CFR 524.1044h to reflect the approval.

The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

The agency has determined under 21 CFR 25.33(a)(4) 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 Subject 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.

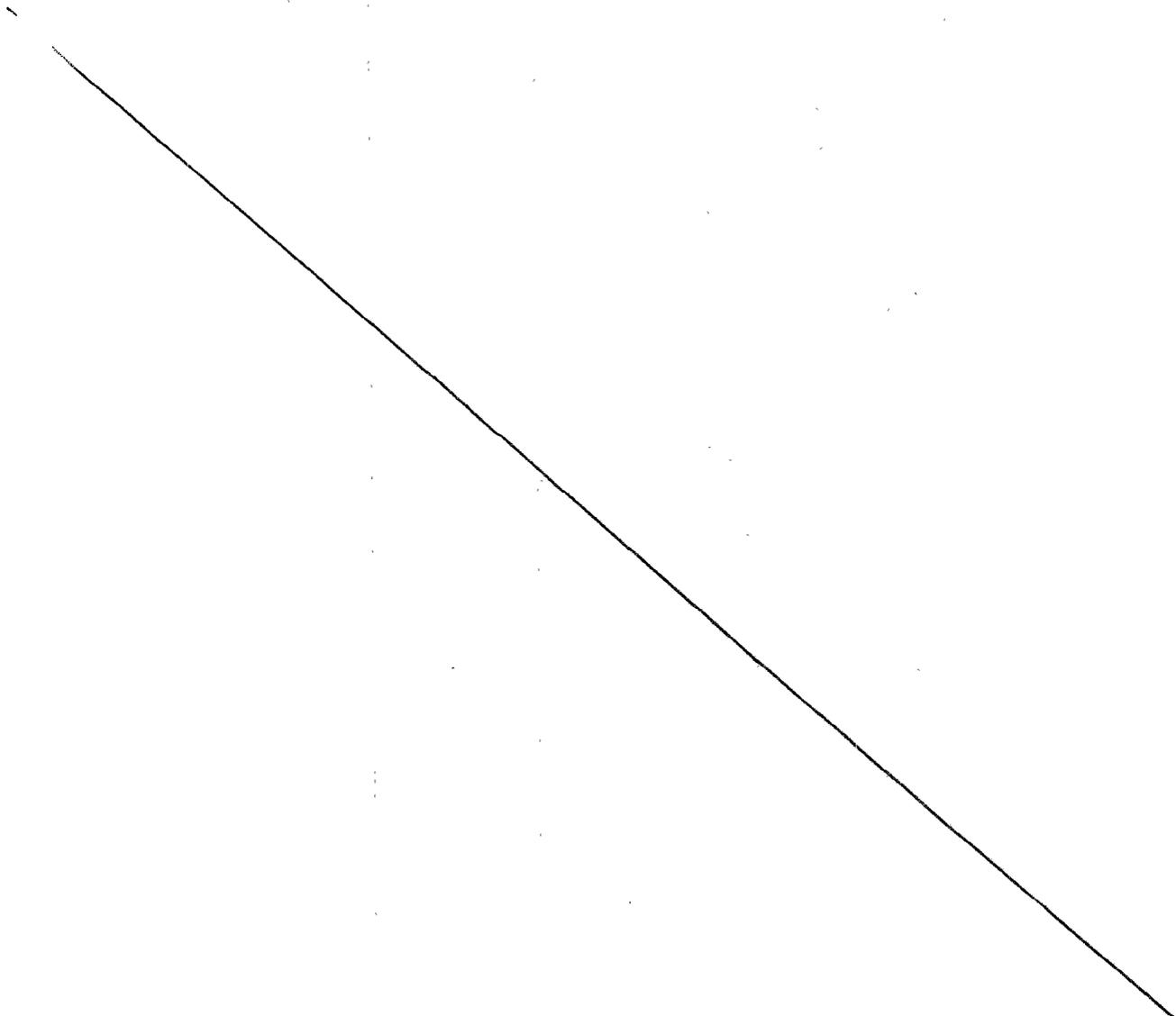
■ 2. Section 524.1044h is amended by revising paragraphs (b) and (c)(1) to read as follows:

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

* * * * *

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or



more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

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Dated: June 15, 2005
June 15, 2005.

Steven D. Vaughn

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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