

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment; 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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for a new container size, a 20-gram dropper bottle, from which gentamicin sulfate, betamethasone valerate, clotrimazole ointment may be administered for the treatment of acute and chronic canine otitis externa. The regulations are also being amended to correct the indications for use to agree with approved product labeling. 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: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200-287 for use of TRIPLEMAX (gentamicin sulfate, U.S.P.; betamethasone valerate, U.S.P.; and

clotrimazole, U.S.P. ointment) for the treatment of acute and chronic canine otitis externa. The supplement provides for a new container size, a 20-gram dropper bottle. The supplemental ANADA is approved as of January 21, 2005, 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.

The regulations are also being amended to correct the indications for use to agree with approved product labeling. This action is being taken to improve the accuracy of the regulations.

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 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 524.1044g is amended by revising paragraphs (b)(3), (c)(1)(ii), and (c)(2) to read as follows.

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

* * * * *

(b) * * *

(3) No. 059130 for use of 10-, 20-, or 215-g bottles.

(c) * * *

(1) * * *

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

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Dated: February 8, 2005.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S