

Date of Approval: November 10, 2011

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-416

Gentamicin Topical Spray

(gentamicin sulfate, betamethasone valerate)

Dogs

For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.

Sponsored by:

Sparhawk Laboratories, Inc.

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I. GENERAL INFORMATION:

- A. File Number:** ANADA 200-416
- B. Sponsor:** Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

Drug Labeler Code: 058005
- C. Proprietary Name:** Gentamicin Topical Spray
- D. Established Names:** Gentamicin sulfate, betamethasone valerate
- E. Pharmacological Category:** Antimicrobial, anti-inflammatory
- F. Dosage Form:** Spray
- G. Amount of Active Ingredients:** Each milliliter of spray contains gentamicin sulfate, USP equivalent to 0.57 mg of gentamicin base and betamethasone valerate, USP equivalent to 0.284 mg of betamethasone.
- H. How Supplied:** 60 mL, 120 mL, and 240 mL
- I. How Dispensed:** Rx
- J. Dosage:** Two depressions of the sprayer head 2 to 4 times daily for 7 days
- K. Route of Administration:** Topical
- L. Species/Class:** Dogs
- M. Indication:** For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.
- N. Reference Listed New Animal Drug** GENTOCIN Topical Spray; gentamicin sulfate, betamethasone valerate; NADA 132-338; Intervet, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Sparhawk Laboratories, Inc. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Gentamicin Topical Spray (gentamicin sulfate, betamethasone valerate). The generic product is a solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The RLNAD is GENTOCIN Topical Spray (gentamicin sulfate, betamethasone valerate), sponsored by Intervet, Inc. under NADA 132-338, and was approved for use in dogs for the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin on January 7, 1985.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Gentamicin Topical Spray:

Keep out of reach of children.

VII. AGENCY CONCLUSIONS:

The information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Gentamicin Topical Spray, when used according to the label, is safe and effective in dogs for the treatment of infected superficial lesions caused by bacteria susceptible to gentamicin.