

Approval Date: January 12, 2007

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-415

**Gentamicin Sulfate Topical Spray
(gentamicin sulfate, USP with betamethasone valerate, USP)**

**Indicated for the treatment of infected superficial lesions in
dogs caused by bacteria susceptible to gentamicin**

Sponsored by:

First Priority, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-415
- b. Sponsor: First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123
- Drug Labeler Code: 058829
- c. Established Name: Gentamicin sulfate,
betamethasone valerate
- d. Proprietary Name: Gentamicin Sulfate Topical Spray
- e. Dosage Form: Liquid
- f. How Supplied: 60 mL, 120 mL, and 240 mL spray bottles
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each mL contains: gentamicin sulfate,
USP equivalent to 0.57 mg gentamicin
base, betamethasone valerate, USP
equivalent to 0.284 mg betamethasone.
- i. Route of Administration: Topical
- j. Species/Class: Dogs
- k. Recommended Dosage: Two depressions of the sprayer head 2 to 4
times daily for 7 days. Each depression of
the sprayer head delivers 0.7 mL of
Gentamicin Sulfate Topical Spray.
- l. Pharmacological Category: Antimicrobial
- m. Indications: For the treatment of infected superficial
lesions in dogs caused by bacteria
susceptible to gentamicin.
- n. Pioneer Product: GENTOCIN Topical Spray (gentamicin
sulfate, betamethasone valerate) NADA
132-338; Schering-Plough Animal Health
Corporation

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). 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 pioneer, 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, First Priority, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Gentamicin Sulfate Topical Spray (gentamicin sulfate, betamethasone valerate). The generic product is administered as a topical, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, GENTOCIN Topical Spray (gentamicin sulfate, betamethasone valerate) the subject of Schering-Plough Animal Health Corp, NADA 132-338, was approved on January 7, 1985.

3. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that GENTOCIN Topical Spray, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-415:

Product label, 60 mL package size

Product label, 120 mL package size

Product label, 240 mL package size

Package Insert

Pioneer Labeling for NADA 132-338:

Product label, 72 mL package size

Package insert

Product case, 72 mL package size