Date of Approval: April 7, 2009

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-388

GB Topical Spray
(gentamicin sulfate and betamethasone valerate)

Dogs

Indications: GB Topical Spray is used for the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.

Sponsored by:

American Pharmaceuticals & Cosmetics, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-388
b. Sponsor:	American Pharmaceuticals & Cosmetics, Inc. 1401 Joel East Road Fort Worth, TX 76140 Drug Labeler Code: 065531
c. Established Name:	Gentamicin sulfate and betamethasone valerate
d. Proprietary Name:	GB Topical Spray
e. Dosage Form:	Topical solution
f. How Supplied:	60 mL, 120 mL, and 240 mL spray bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredient:	Each mL contains: gentamicin sulfate, USP equivalent to 0.57 mg gentamicin base and betamethasone valerate, USP equivalent to 0.284 mg betamethasone.
i. Route of Administration:	Topical
j. Species/Class:	Dogs
k. Recommended Dosage:	Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer 2 to 4 times daily for 7 days. Each depression of the sprayer head delivers 0.7 ml of **Gentamicin Sulfate With Betamethasone Valerate 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 Corp.

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, American Pharmaceuticals & Cosmetics. Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product GB Topical Spray (gentamicin sulfate, betamethasone valerate). The generic product is administered as a topical solution, 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 (gentamicin sulfate, betamethasone valerate) Topical Spray 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.

Human Warnings are provided on the product label as follows: "**For Animal Use Only**", "**Keep Out of Reach of Children**".

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 indicated below:

Generic Labeling for ANADA 200-388:
Bottle label and outsert, 60 mL package size, and 60 mL dozen carton
Bottle label and outsert, 120 mL package size, and 120 mL dozen carton
Bottle label and outsert, 240 mL package size, and 240 mL dozen carton

Pioneer Labeling for NADA 132-338:
Product label, 72 mL package size
Package insert
72 mL dozen carton