Approval Date: January 29, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-188

B. Sponsor

Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

C. Proprietary Name

Betagen™ Topical Spray

D. Established Name

gentamicin sulfate and betamethasone valerate topical spray

E. Dosage Form

Solution

F. Amount of Active Ingredient

Each mL contains gentamicin sulfate equivalent to 0.57 mg gentamicin base and betamethasone valerate equivalent to 0.284 mg betamethasone, 163 mg isopropyl alcohol, propylene glycol, methylparaben and propylparaben as preservatives, purified water q.s., Hydrochloric acid may be added to adjust pH.

G. How Supplied

Spray bottles of 120 mL and 240 mL

H. Dispensing Status

Rx

I. Route of Administration

Topical

J. Species/Class

Dogs

K. Indication

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

L. Pioneer Product

Gentocin Topical Spray (gentamicin sulfate with betamethasone valerate, NADA 132-338) by Schering- Plough Animal Health Corporation

II. 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, (53 FR 50460, December 15, 1988; First GADPTRA Policy Letter), an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Med-Pharmex Inc was granted a waiver September 8, 1992 from conducting an *in vivo* bioequivalence study with Gentocin Topical Spray. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient. It is intended for topical administration.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption
Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. This drug is labeled for use in dogs only and should not be administered to food-producing animals.

Human Safety Relative to Possession, Handling, and Administration
Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This is an abbreviated new animal drug application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Betagen Topical Spray, were established by demonstration of chemical equivalence to the pioneer product, Schering-Plough Animal Health Corporation's GentocinTopical Spray (NADA 132-338). This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered topically. The generic and pioneer products are both solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or in vivo bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Betagen Topical Spray is safe and effective for its labeled indications when used under its proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.