Approval Date: April 4, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-229

B. Sponsor

Med-Pharmex, Inc.

C. Proprietary Name

Tri-Otic Ointment

D. Established Name

Gentamicin Sulfate, Betamethasone Valerate and Clotrimazole Ointment

E. Dosage Form

Tri-Otic Ointment is an external ointment.

F. Dispensing Status

Rx

G. Route of Administration

Instill 4 drops (2 drops from the 215 g bottle) twice daily into the ear canal of dogs weighing less than 30 lbs. Instill 8 drops (4 drops from the 215 g bottle) twice daily into the ear canal of dogs weighing 30 lbs. or more. Therapy should continue for 7 consecutive days.

Contraindications: If hypersensitivity to any of the components occurs, treatment with this product should be discontinued and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided. Do not use in dogs with known perforation of eardrums.

H. Indication

Tri-Otic Ointment is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (Malassezia pachydermatis, formerly Pityrosporum canis) and/or bacteria susceptible to gentamicin.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

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). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Rather, approval of an ANADA relies on the ANADA sponsor showing that the generic

product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June18,1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Tri-Otic Ointment (gentamicin sulfate, betamethasone valerate and clotrimazole ointment). The generic product is administered as a topical ointment and contains the same active and inactive ingredients in the same concentrations as the pioneer product.

III. HUMAN FOOD SAFETY

This drug is indicated for use only on dogs. It is not to be used for food-producing animals. Therefore, the issue of residues and human safety does not arise.

IV. 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 Tri-Otic Ointment (gentamicin sulfate, betamethasone valerate and clotrimazole ointment) when used under its proposed conditions of use, is safe and effective for the labeled indications.

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.