Approval Date: February 27, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-229

TRI-OTIC Ointment
(gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP)

For the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin

Sponsored by:

Med-Pharmex, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-229
b. Sponsor:	Med-Pharmex, Inc. 2727 Thompson Creek Rd Pomona, CA 91767-1861 Drug Labeler Code: 054925
c. Established Name:	Gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP
d. Proprietary Name:	TRI-OTIC
e. Dosage Form:	Ointment
f. How Supplied:	7.5-gram and 15-gram tubes 10-gram, 15-gram, 25-gram, and 215-gram plastic bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each gram contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; betamethasone valerate,USP equivalent to 1 mg betamethasone; and 10 mg clotrimazole, USP in a mineral oil-based system.
i. Route of Administration:	Topical
j. Species/Class:	Dogs
k. Recommended Dosage:	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.
l. Pharmacological Category:	Antibiotic, anti-inflammatory, anti-pruritic, and antifungal

m. Indications:	For the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.
n. Pioneer Product:	OTOMAX; gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP; NADA 140-896; Schering-Plough Animal Health Corp.
o. Effect of Supplement:	The addition of a 15 gram bottle package size made from a new material MDPE, instead of the existing LDPE or HDPE used in other sizes.

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 shows 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, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product TRI-OTIC (gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP) Ointment. The generic product is administered as an ointment, 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, OTOMAX (gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP) Ointment, the subject of Schering-Plough Animal Health Corp., NADA 140-896, was approved on June 9, 1993.

3. HUMAN 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, data on human safety pertaining to drug residues in food were not required for approval or this ANADA.

Human Warnings are provided on the product label as follows: "**Keep Out of Reach of Children"** and "**For otic use in dogs only"**.

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 OTOMAX Ointment, 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 200-229:
TRI-OTIC Ointment
15 g bottle label
Package Insert
15 g carton

Pioneer Labeling for NADA 140-896:
OTOMAX Ointment
15 g bottle label
Package Insert
15 g carton