Date of Approval: January 21, 2005

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-287

TRIPLEMAX
(gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP Ointment)

For otic use in dogs only

TRIPLEMAX 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.

Sponsored by:

Phoenix Scientific, Inc.

1. GENERAL INFORMATION

a. File Number:	ANADA 200-287
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP
d. Proprietary Name:	TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment)
e. Dosage Form:	Ointment
f. How Supplied:	10-gram, 20-gram and 215-gram plastic bottles.
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each gram of TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP, ointment) 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 containing a plasticized hydrocarbon gel.
i. Route of Administration:	Topical
j. Species/Class:	Dogs
k. Recommended Dosage:	Instill 2 drops of TRIPLEMAX twice daily to the ear canal of dogs weighing less than 30 lbs. Instill 4 drops twice daily into the ear canal of dogs weighing 30 lbs or more. Therapy should continue for 7 consecutive days.

l. Pharmacological Category:	Antibacterial, anti-inflammatory, and antifungal.
m. Indications:	TRIPLEMAX 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.
n. Pioneer Product:	OTOMAX Ointment; gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP; NADA 140-896; Schering-Plough Animal Health Corp.
o. Effect of Supplement:	This supplement provides for an additional package size, 20-gram fill in a 30 mL bottle. The bottle will be the same LDPE as the approved 15 mL bottle, and the plug, dropper and cap will be the exact same closure as the approved package.

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, Phoenix Scientific, Inc., was granted a waiver from the requirements for an *in vivo* bioequivalence study for the generic product TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and Clotrimazole, USP Ointment). The generic product is administered as an ointment, contains the same active ingredient 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 OTOTMAX (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 of this ANADA.

Human Warnings are provided on the product label as follows: "For Otic Use in Dogs Only. Keep this and all drugs out of reach of children."

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP 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:

<u>Generic Labeling for ANADA 200-287:</u>

TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment);
- 20 gram bottle label
- Package insert

<u>Pioneer Labeling for NADA 140-896:</u>

OTOMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment);
- Package insert
- 15 gram bottle label
- 15 gram bottle individual carton