Date of Approval: August 23, 2006

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-287

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

For use in dogs only

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:

IVX Animal Health, Inc.

1. GENERAL INFORMATION:

a. ANADA Number:	ANADA 200-287
b. Sponsor:	IVX Animal Health, Inc. 3915 South 48th Street Ter. St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP
d. Proprietary Name:	TRIPLEMAX
e. Dosage Form:	Ointment
f. How Supplied:	10 g, 20 g, 40 g, and 215 g bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredient:	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; gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP; NADA 140-896; Schering-Plough Animal Health Corp.
o. Effect of Supplement:	The effect of the supplement is to add an additional package size, 40 g fill in a 2 oz. bottle.

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 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 Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product, IVX Animal Health, Inc. was granted a waiver from the requirement of 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 a topical ointment, contains similar 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 of this ANADA.

Human Warnings are provided on the product label as follows: **"Keep Out of Reach of Children**".

4. AGENCY CONCLUSIONS:

This ANADA filed 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 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 200-287:
TRIPLEMAX Ointment product label (40 g)
TRIPLEMAX Ointment carton (40 g)
TRIPLEMAX Ointment package insert

Pioneer Labeling for NADA 140-896:
OTOMAX Ointment product label (15 g)
OTOMAX Ointment carton (15 g)
OTOMAX Ointment package insert
OTOMAX Ointment product label (215 g)