Date of Approval: March 28, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-287

Indications for use: GBC Ointment™ is used in 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.
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. ANADA Number	200-287
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, MO 64503 21 CFR 510.600: Labeler Code: 059130
c. Established Name:	Gentamicin Sulfate, Betamethasone Valerate and Clotrimazole Ointment
d. Trade/Proprietary Name:	GBC Ointment™
e. Dosage Form:	Ointment
f. How Supplied:	10 gram and 215 gram plastic bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each gram: 3 mg gentamicin base, 1 mg betamethasone and 10 mg clotrimazole, USP in mineral oil base system.
i. Route of Administration:	Topical
j. Species:	Dogs
k. Labeled Dosage and Administration:	Instill 2 drops of GBC Ointment™ twice daily into ear canal of dogs weighing less than 30 lbs and 4 drops of GBC Ointment™ twice daily into the ear canal of dogs weighing 30 lbs or more.

l. Indications for Use:	Treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis,* formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin
m. Pharmacological Category:	Antibacterial, Antifungal
n. Pioneer Product:	Otomax® manufactured by Schering-Plough Animal Health (NADA 140-896)

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 drug 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 conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on May 5, 1997, from the requirement of an *in vivo* bioequivalence study for GBC Ointment™. The generic and pioneer products contain the same active and inactive ingredients in a similar formulation as the pioneer. The pioneer product, Otomax®, the subject of Schering-Plough Animal Health's NADA 140-896 was approved on June 9, 1993.

3. HUMAN SAFETY:

This drug is indicated for use only 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 NADA.

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

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 GBC Ointment™ when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. Attachments:

Labeling: Pioneer Labeling for NADA 140-896:
Otomax®-7.5, 12.5 g, 15g, 30g, 215g

Generic Labeling for ANADA 200-287

(AmTech's) GBC™- 10 gram and 215 gram bottles
Insert

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.