Approval Date: November 17, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-394

Gentamicin Piglet Injection
(gentamicin sulfate)

Indicated for the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin

Sponsored by:

Sparhawk Laboratories, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number	ANADA 200-394
b. Sponsor:	Sparhawk Laboratories, Inc. 12340 Santa Fe Trail Drive Lenexa, KS 66215 Drug Labeler Code: 058005
c. Established Name:	Gentamicin sulfate
d. Proprietary Name:	Gentamicin Piglet Injection
e. Dosage Form:	Injection
f. How Supplied:	100 mL, 250 mL, and 500 mL multiple dose vials
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each mL contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base
i. Route of Administration:	Intramuscular
j. Species/Class:	Swine, piglets only up to 3 days of age
k. Recommended Dosage:	1 mL per piglet
l. Pharmacological Category:	Antimicrobial
m. Indications:	For the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin
n. Pioneer Product:	GARACIN Piglet Injection; Gentamicin sulfate; NADA 103-037; Schering-Plough Animal Health Corp.

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, Sparhawk Laboratories, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Gentamicin (gentamicin sulfate) Piglet Injection. The generic product is administered as an injection, 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, GARACIN (gentamicin sulfate) Piglet Injection the subject of Schering-Plough Animal Health Corp, NADA 103-037, was approved on January 7, 1983.

3. HUMAN SAFETY:

- **Tolerances for Residues:**

  The tolerance established for the pioneer product applies to the generic product. A tolerance 0.1 part per million (ppm) in muscle, 0.3 ppm in liver, and 0.4 ppm in fat and kidney is established for gentamicin residues in the uncooked edible tissues of swine under 21 CFR 556.300.

- **Withdrawal Times:**

  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product (21 CFR 522.1044).

  The withdrawal time is at least 40 days following treatment.

- **Regulatory Method for Residues:**

  The procedure for the determination of gentamicin in tissues is a microbiological determinative procedure and an HPLC confirmatory procedure for gentamicin have been developed to assay gentamicin in kidney at 0.4 ppm. Since residues of gentamicin as the parent compound and total residues are equal, the marker (parent drug) residue concentration of 0.4 ppm in kidney corresponds to 0.4 ppm of total residue. The validated methods are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This original 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 GARACIN Piglet Injection, 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 200-394:
Product label and outsert, 100 mL package size
Product label and outsert, 250 mL package size
Product label and outsert, 500 mL package size

Pioneer Labeling for NADA 103-037:
Product label, 250 mL package size
Package insert
Product carton, 250 mL package size