Approval Date: October 24, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-379

Neomycin Liquid
(neomycin sulfate)

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* in cattle, swine, sheep, and goats.

Sponsored by:

Sparhawk Laboratories, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-379
b. Sponsor:	Sparhawk Laboratories, Inc. 12340 Santa Fe Trail Dr. Lenexa, KS 66215 Drug Labeler Code: 058005
c. Established Name:	Neomycin sulfate
d. Proprietary Name:	NEOMYCIN Liquid
e. Dosage Form:	Solution
f. How Supplied:	16 Fl oz. (473 mL) bottle 1 Gallon (3.785L) jug
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each mL contains neomycin sulfate (commercial grade) 200 mg equivalent to 140 mg neomycin
i. Route of Administration:	Oral
j. Species/Class:	Cattle, swine, sheep, and goats
k. Recommended Dosage:	Administer to cattle, swine, sheep, and goats at a dose of 10 mg neomycin sulfate per pound of body weight in divided doses for a maximum of 14 days.
l. Pharmacological Category:	Antibacterial
m. Indications:	For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep, and goats.
n. Pioneer Product:	BIOSOL Liquid; neomycin sulfate; ANADA 200-113; Pharmacia & Upjohn Co., a Division of Pfizer, Inc.

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, Sparhawk Laboratories, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Neomycin Liquid (neomycin sulfate). The generic product is administered as an oral solution, 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 BIOSOL (neomycin sulfate) Liquid, the subject of Pharmacia & Upjohn Co., a Division of Pfizer, Inc. ANADA 200-113, was approved on June 28, 1993.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerances are established for the pioneer product applies to the generic product. Tolerances are established for residues of the parent neomycin in uncooked edible tissues of cattle, swine, sheep and goats at 7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, and 1.2 ppm in muscle under 21CFR 556.430. The ADI for total residues of neomycin is 6 micrograms per kilogram of body weight.

- **Withdrawal Times:**
  Because a waiver of the in vivo bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal times are; Cattle-1 day, Sheep-2days, Swine and Goats-3 days (21 CFR 520.1485).

- **Regulatory Method for Residues:**
  The regulatory analytical method for detection of residues of the drug is a microbiological test using *Staphylococcus epidermidis* suspension. The method is published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols", revised October 1968, reprinted December 1974.

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 Neomycin Liquid, 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 200-379:
16 Fl. Oz (473 mL) bottle
1 Gallon

Pioneer Labeling for ANADA 200-113:
16 Fl Oz (473 mL) bottle