Approval Date: August 31, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-378

Neomycin Sulfate 325
(neomycin sulfate)

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

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.

Sponsored by:

Sparhawk Laboratories, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number	ANADA 200-378
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 Sulfate 325
e. Dosage Form:	Soluble Powder
f. How Supplied:	3.5 oz (100 grams) packet Pail containing 50 packets
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each packet contains 71.5 gm neomycin sulfate (commercial grade) equivalent to 50 mg neomycin
i. Route of Administration:	Oral
j. Species/Class:	Cattle, swine, sheep, goats, and turkeys
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. Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day for 5 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. For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.
n. Pioneer Product:	NEOMIX 325 Soluble Powder; neomycin sulfate; NADA 11-315; 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 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 Neomycin Sulfate 325 (neomycin sulfate). The generic product is administered as a soluble powder, 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, NEOMIX 325 (neomycin sulfate) Soluble Powder the subject of Pharmacia & Upjohn Co., a Division of Pfizer, Inc., NADA 011-315 was approved on March 21, 1958.

3. HUMAN SAFETY:

Human Warnings are provided on the product label as follows: “Not for human use. Keep out of reach of children.”

- **Tolerances for Residues:**

  The tolerances 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, goats, and turkeys 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 21 CFR 556.430. The established Acceptable Daily Intake (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 0 day for turkeys, one day for cattle, 2 days for sheep, and 3 days for swine and goats (21 CFR 520.1484).

- **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 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 Neomycin Sulfate 325, 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 200-378:
Packet label 3.5 oz (100 grams)
Pail Label

Pioneer Labeling for NADA 011-315:
Container Label 50 lb (22.6 kg)