Approval Date: October 25, 2002

FREEDOM OF INFORMATION SUMMARY

Supplemental ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-130

Neo-Sol® 50 (neomycin sulfate)

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

Sponsored by:
Alpharma, Inc.
Fort Lee, NJ 07024

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

ANADA	200-130
Sponsor:	Alpharma, Inc. One Executive Drive Fort Lee, NJ 07024
Generic Name:	neomycin sulfate
Trade Name:	Neo-Sol® 50
Marketing Status:	Over The Counter
Supplemental Effect:	To provide for turkeys as an additional approved species based upon approval of turkeys in the pioneer product, and expiration of exclusivity period.
Pioneer:	Pharmacia and Upjohn Company/Neomix® 325 NADA 011-315

II. INDICATIONS FOR USE:

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 (new).

III. DOSAGE:

A. Dosage Form:	Soluble Powder
B. How Supplied:	3.5 oz (100 g) packet
C. Amount of Active Ingredient:	Neomycin sulfate soluble powder contains 71.5 grams of neomycin sulfate (equivalent to 50 grams of neomycin) per packet.

D. Route of Administration	Orally in drinking water (turkeys) or milk and water (other species).

E. Species: Cattle (excluding veal calves), Swine, Sheep, Turkeys (new), and Goats.

F. Labeled Dosage: Cattle, Swine, Sheep, and Goats - 10 mg/lb body weight (22 mg/kg) daily in divided doses for a maximum of 14 days.

Growing Turkeys – 10 mg/lb body weight (22 mg/kg) daily for a maximum of 5 days.

IV. 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 is 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, the sponsor was granted a waiver on December 1, 1993, from conducting an *in vivo* bioequivalence study for Neo-Sol® 50 and the generic product was approved on May 8, 1996. The generic product is administered as an oral solution and contains the same active ingredient and drug concentration as the pioneer and contains no inactive ingredients that may significantly affect the absorption of the active ingredient.

The basis for this supplemental ANADA approval was published in 64 FR 31498, June 11, 1999, and provided for the use of neomycin sulfate in turkey drinking water for the control of mortality claim. The exclusivity period for turkeys expired on May 9, 2002, for the pioneer product, NADA 011-315.

V. HUMAN FOOD SAFETY:

Tolerances:

The tolerances established for the pioneer product apply to the generic product. Neomycin residues in the uncooked edible tissues of cattle, swine sheep, goats and turkeys as published in 21 CFR 556.430 are:

7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, and 1.2 ppm in muscle of cattle (except veal calves), swine, sheep, and goats and a tolerance of 0.15 ppm is established in milk.

7.2 parts per million (ppm) in skin with adhering fat, 3.6 ppm in liver, and 1.2 ppm in muscle of turkeys.

Withdrawal Times (21 CFR 520.1484):

Cattle (excluding veal calves)	1 Day
Swine	3 Days
Goats	3 Days
Sheep	2 Days
Turkeys	0 Days

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. The method is available from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville Maryland 20855.

VI. AGENCY CONCLUSIONS:

This 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 Neo-Sol® 50 when used under its proposed conditions of use, is safe and effective for its labeled indications.

Attachments: **Pioneer Labeling:**

3.5 oz (100 grams) packet

Generic Labeling:

3.5 oz (100 grams) packet

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.