FREEDOM OF INFORMATION (FOI) SUMMARY

NEORAL (neomycin oral solution)

ANADA 200-289

Med-Pharmex, Inc.

2727 Thompson Creek Road

Pomona, CA 91767-1861

Date of Approval July 3, 2000

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

ANADA 200-289

ANADA Sponsor:
Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

A. Established Name:	neomycin sulfate
B. Trade/Proprietary Name:	Neoral Oral Solution
C. Dosage Form:	oral solution
D. How Supplied:	473.1 mL (1 Pt), 3.785 L (1 Gal)
E. How Dispensed:	OTC
F. Amount of Active Ingredients:	200 mg of neomycin sulfate per mL (140 mg neomycin base per mL).
G. Route of Administration:	Orally in drinking water or milk
H. Species:	Cattle (excluding veal calves), Swine, Sheep, and Goats.
I. Labeled Dosage:	Administer to cattle (excluding veal calves), 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.
J. Pharmacological Category:	Antibiotic
K. Indications for Use:	For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.
L. Pioneer/NADA #:	Pharmacia & Upjohn Company, Neomix® 325, NADA 011-315

II. 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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, April 1990).

An oral solution as a generic copy of a soluble powder is a change in dosage form that is permissible under the GADPTRA. On October 1, 1992, a suitability petition (92P-0363/CP1) was approved to allow a generic sponsor (Phoenix Scientific, Inc.) to file an ANADA for a neomycin oral solution as a generic copy of the pioneer (Pharmacia & Upjohn) neomycin sulfate soluble powder, Neomix® 325, NADA 11-315. Relying on the conclusions of suitability petition (92P-0363/CP1), Med-Pharmex's generic product is approved as a copy of the pioneer product sponsored by Pharmacia & Upjohn Company.

Based upon the formulation characteristics of the generic product, Med-Pharmex was granted a waiver from conducting an *in vivo* bioequivalence study for neomycin sulfate. The generic and pioneer products contain the same active ingredient, and no differences in the inactive ingredients which would affect bioavailability of the active ingredient. The pioneer and generic products are administered as oral solutions.

The generic product is formulated as a solution, and the pioneer product is formulated as a water soluble powder. The generic product is formulated at 200 mg neomycin sulfate/mL, and the pioneer product is formulated at 325 g neomycin sulfate/pound of product. The pioneer and generic products will be administered as oral solutions in water or milk, at a dosage of 10 mg neomycin sulfate per pound body weight in divided doses for a maximum of 14 days.

III. HUMAN FOOD SAFETY

Tolerance

A tolerance of 7.2 parts per million (ppm) is established for residues of parent neomycin (marker residue) uncooked edible kidney (target tissue 7.2 ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk (21 CFR 556.430).

Withdrawal Period

When a waiver of *in vivo* bioequivalence testing is granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal times are 1 day for cattle, 3 days for swine and goats, and 2 days for sheep.

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.

IV. 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 neomycin sulfate oral solution when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments: The following generic labeling and currently approved pioneer labeling are attached.

1. Facsimile package label for Neoral Oral Solution for 473.1 mL (1 Pt), and 3.785 L (1 Gal).

2. Approved pioneer package label for neomycin sulfate - Neomycin 325 Soluble Powder for 3.5 oz packages and 50 LB bags.