Approval Date: March 9, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-235

B. Sponsor

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

C. Proprietary Name

Neosol Soluble Powder

D. Established Name

neomycin sulfate soluble powder

E. Dispensing Status

OTC

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

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. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June18,1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Neosol Soluble Powder (neomycin sulfate soluble powder). The generic product is administered as an oral solution and contains the same active and inactive ingredients in the same concentration as the pioneer product.

III. HUMAN FOOD SAFETY

Tolerance
The tolerance established for the pioneer product apply to the generic product. The

tolerances established for neomycin residues in the uncooked edible tissues of cattle, swine, sheep, and goats are 1.2 ppm in muscle, 3.6 ppm in liver, 7.2 ppm for kidney (target tissue), and 7.2 ppm in fat, (21 CFR 556.430).

Withdrawal Time
When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal times are 3 days for swine and goats, 2 days for sheep, and 1 day for cattle (excluding veal calves) (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* 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 soluble powder (Neosol Soluble Powder) when used under its proposed conditions of use, is safe and effective for the labeled indications.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.