Approval Date: May 15, 1992

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-046

B. Sponsor

Pfizer Inc.
235 East 42nd Street
New York, New York 10017

C. Proprietary Name

Neomycin Soluble Powder 325 gm/lb

D. Established Name

neomycin sulfate

E. Dosage Form

Soluble Powder

F. Dispensing Status

OTC

G. Dosage Regimen

The drug is administered at 10 mg neomycin sulfate per pound of body weight (equivalent to 7 mg neomycin base) per day in divided doses for a maximum of 14 days.

H. Route of Administration

Neomycin Soluble Powder is administered orally in water or milk.

I. Indication

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

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Under the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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, and the ANADA relies on the target

animal safety and effectiveness and human food safety data (other than tissue residue data) in the new animal drug application (NADA) for 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 the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Pfizer was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product, Neomycin Soluble Powder. 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 absorption of the active ingredient. The pioneer product is Neomix 325 (neomycin sulfate soluble powder) the subject of the Upjohn Company's NADA 11-315, approved on March 21, 1958, as upgraded by the approval on March 4, 1992 (see 57 FR 19084; May 4, 1992), of a supplemental NADA bringing the product into compliance with FDA conclusions, based in part on the National Academy of Sciences/National Research Council Drug Efficacy Study Group evaluation of the product, regarding indications for use and labeling, among other things.

III. HUMAN FOOD SAFETY

Tolerance

The tolerance established for the pioneer product apply to the generic product. A tolerance of 0.25 ppm is already established for edible tissues of cattle (excluding veal calves), swine, sheep and goats, and a tolerance of 0.15 ppm for milk (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 for neomycin sulfate soluble powder are established in 21 CFR 558.20: 30 days for cattle (excluding veal calves), goats and 20 days for swine and 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 as 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 satisfies the requirements of section 512 of the act and demonstrates that neomycin sulfate soluble powder, when used under its proposed conditions of use, is safe and effective for the labeled indications. The approval provides for use of neomycin sulfate soluble powder for the treatment and control of colibacillosis (bacterial enteritis) caused by Escherichia coli susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep, and goats.

Neomycin sulfate soluble powder (the pioneer product) for use in food-producing animals is currently on the market as an over-the-counter product. Therefore, the Center for Veterinary Medicine has concluded that this generic product should have over-the-counter marketing status.

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.