Approval Date: February 15, 1995

# FREEDOM OF INFORMATION SUMMARY

## I. GENERAL INFORMATION

### A. File Number

ANADA 200-050

### B. Sponsor

Sanofi Animal Health, Inc.
P.O. Box 459
Ft. Dodge, Iowa 50501

### C. Proprietary Name

Neomycin 325 Soluble Powder

### D. Established Name

neomycin sulfate

### E. Dosage Form

Soluble powder

### F. Amount of Active Ingredient

25 g neomycin/1.76 oz, 50 g neomycin/3.5 oz

### G. How Supplied

1.76 oz (50 g) and 3.5 oz (100 g) packages

### H. Dispensing Status

OTC

### I. Dosage Regimen

10 mg/lb body weight daily in divided doses for a maximum of 14 days

### J. Route of Administration

Orally in drinking water or milk

### K. Indication

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.

## 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 (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Sanofi Animal Health, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for neomycin sulfate soluble powder. The generic product is administered as an oral solution and contains the same active ingredient and drug concentration as the pioneer product. The generic product is the same dosage form as the pioneer and contains no inactive ingredients that may significantly affect the absorption of the active ingredient.

## III. HUMAN FOOD SAFETY

### Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.25 ppm is established for neomycin residues in the uncooked edible tissues of cattle, swine, sheep, and goats and a tolerance of 0.15 ppm is established for 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 30 days for cattle (excluding veal calves) and goats and 20 days for swine and sheep (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.

## 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 when used under the proposed conditions of use, is safe and effective for its 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.