Approval Date: June 28, 1993

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-113

B. Sponsor

The Upjohn Company
Kalamazoo, Michigan 49001-0199

C. Proprietary Name

Biosol® Liquid

D. Established Name

Neomycin sulfate

E. Dosage Form

Oral solution

F. Amount of Active Ingredient

200 mg neomycin sulfate/mL equivalent to 140 mg neomycin/mL

G. How Supplied

16 Fluid Ounces (1 pint)

H. Dispensing Status

OTC

I. Dosage Regimen

10 mg neomycin sulfate per pound of body weight in divided doses for a maximum of 14 days

J. Route of Administration

Oral

K. Indication

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

L. Reference Listed New Animal Drug

The 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. 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).

The generic product was the subject of an approved suitability petition (92P-0057/CP1), in which the agency granted permission to The Upjohn Company to file an ANADA for changes in dosage form and in strength, relative to the pioneer product. 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 of body weight in divided doses for a maximum of 14 days.

As a separate action, based upon the formulation characteristics of the pioneer and generic products, The Upjohn Company was granted a waiver from conducting an in vivo bioequivalence study. The pioneer and generic products will be administered as oral solutions at the same dosage, and the generic product does not contain any inactive ingredients that may significantly affect absorption of the active ingredient.

III. HUMAN FOOD SAFETY

Tolerance for the marker residue
The tolerance established for the pioneer product applies to the generic product as well.

A tolerance of 0.25 ppm has already been established for edible tissues of calves and 0.15 ppm for milk (21 CFR 556.430). The tolerance of 0.25 ppm in edible tissues also applies to swine, sheep, and goats. The tolerance of 0.15 ppm for milk also applies to lactating goats.

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

The withdrawal periods which apply to the pioneer product (21 CFR 558.20), 30 days in cattle (excluding veal calves) and goats and 20 days in swine and sheep, are likewise applicable to the generic product.

Regulatory Method
The regulatory analytical method for detection of drug residues is a microbiological test using a suspension of Staphylococcus epidermidis. The method, published by the Food

and Drug Administration, is in "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 Biosol ® Liquid (neomycin sulfate oral solution), when used under its 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.