

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-153

B. Sponsor

Rhone Merieux, Inc.
2116 8th Avenue South
Fort Dodge, Iowa 50501

C. Proprietary Name

NEO 200 Oral Solution

D. Established Name

neomycin sulfate

E. Pharmacological Category

Antibiotic

F. Dosage Form

Oral solution

G. Amount of Active Ingredient

200 mg of neomycin sulfate per mL (140 mg neomycin base per mL).

H. How Supplied

473.1 mL (1Pt), 3.785 L (1 Gal)

I. Dispensing Status

OTC

J. Route of Administration

K. Orally in drinking water or milk

L. Species/Class

Cattle (excluding veal calves), Swine, Sheep, and Goats

M. Indication

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

N. Reference Listed New Animal Drug

Upjohn Company, Neomix® 325, NADA 011-315

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, Rhone Merieux 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 was the subject of an approved suitability petition (92P-0255/CP 1), in which the agency granted permission to Rhone Merieux (formerly Sanofi Animal Health, Inc.), to file an ANADA for changes in the dosage form and in strength, relative to the pioneer product. The Suitability Petition was approved in an agency letter dated August 4, 1992. 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

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 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.

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.