Approval Date: July 14, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-118

B. Sponsor

Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
St. Joseph, Missouri 64506-0457

C. Proprietary Name

Neomycin Oral Solution

D. Established Name

Neomycin Sulfate

E. Dosage Form

oral solution

F. Amount of Active Ingredient

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

G. How Supplied

473.1 mL (pt). 3.785 L (1 gal)

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. Species/Class

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

L. Indication

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

M. Effect of Supplement

To revise the withdrawal period to 1 day in cattle 2 days in sheep, and 3 days for swine and goats to be identical to pioneer product.

N. Reference List New Animal Drug

Pharmacia & Upjohn, NeomixÒ 325, NADA 11-315

II. TARGET ANIMAL SAFETY AND EFFECTIVENESS

No new data were required for the approval of this supplement. The basis for this supplemental approval is in the original approval of this ANADA which was approved on November 29, 1994.

III. HUMAN FOOD SAFETY

Based on the formulation characteristics of the pioneer and generic products, Phoenix Scientific, Inc. was granter a waiver from conducting an *in vivo* bioequivalence study when the original ANADA was approved on November 29, 1994. Since that approval, the pioneer Pharmacia & Upjohn, has supplemented their application to change the withdrawal periods for their product, NeomixÒ 325. Phoenix Scientific is supplementing their ANADA with a labels identical to the pioneer labels.

IV. AGENCY CONCLUSIONS

This supplemental application submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act, satisfies the requirements and demonstrates that Neomycin Oral Solution when used under it proposed conditions of use, is safe and effective for the labeled indications and revised withdrawal periods. The withdrawal periods have been changed to 1 day in cattle, 2 days in sheep, and 3 days for swine and goats.

Under the Center's supplemental approval policy, this is a Category II change [21 CFR 514.106(b)(2)(xi)]. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. The change allows for a decrease in the withdrawal period. Accordingly, this approval did not require a reevaluation of the safety or effectiveness data in the parent application.

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.