Approval Date: April 10, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-174

B. Sponsor

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

C. Proprietary Name

Gentamicin Sulfate Pig Pump Oral Solution

D. Established Name

gentamicin sulfate

E. Pharmacological Category

Antibiotic

F. Amount of Active Ingredients

Each mL contains 5 mg of Gentamicin

G. Dispensing Status

OTC

H. Labeled Dosage

Neonatal pigs: 5 mg gentamicin (1 mL) orally per pig one time

I. Route of Administration

Oral

J. Species/Class

Porcine (neonatal)

K. Indication

For treatment of colibacillosis in neonatal pigs 1-3 days of age.

L. Pioneer Product

Garason7 Pig Pump, Gentamicin Sulfate Oral Solution, manufactured by Schering-Plough Animal Health (NADA 130-464)

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). The sponsor of the ANADA must demonstrate that the generic product is bioequivalent to the pioneer product. For certain dosage forms, the Agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). In lieu of in vivo bioequivalence testing, the bioequivalence of the generic product to the pioneer product is based on the demonstrated chemical equivalence.

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver June 27, 1994 (photocopy attached) from conducting an in vivo bioequivalence study with Gentamicin Sulfate Pig Pump Oral Solution. The generic and pioneer products are solutions with the same active and inactive ingredients.

A suitability petition was approved November 3, 1993 to provide for a slightly more concentrated solution of gentamicin sulfate than the pioneer, since both products are designed to deliver an equivalent amount of active drug on a per dose basis.

III. HUMAN FOOD SAFETY

Tolerance
The tolerances established for the pioneer product apply to the generic product. Tolerances are established for total residues of gentamicin in edible tissues of swine as follows: 0.1 part per million in muscle, 0.3 part per million in liver, and 0.4 part per million in fat and kidney. (21 CFR 556.300)

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 time for Gentamicin Sulfate Pig Pump Oral Solution is established under 21 CFR 520.1044 b: 14 days for swine. For use in neonatal swine only.

Regulatory Method for Residues
A microbiological determinative procedure and an HPLC confirmatory procedure for gentamicin have been developed to assay gentamicin in kidney at 0.4 ppm. Since residues of gentamicin as the parent compound and total residues are equal, the marker (parent drug) residue concentration of 0.4 ppm in kidney corresponds to 0.4 ppm of total residue. (21 CFR 556.300)

IV. USER SAFETY

Labeling contains adequate caution/warning statements.

V. AGENCY CONCLUSIONS

This is an Abbreviated New Animal Drug Application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Bioequivalence for this generic animal drug, Gentamicin Sulfate Pig Pump Oral Solution (5 mg/mL), was established by demonstration of chemical equivalence to the pioneer product, Schering-Plough's Garason7 Pig Pump (NADA 130-464).

This generic product and the pioneer product have identical labeling indications for the 118 mL (4 oz) vial for use in pigs (neonatal). The route and method of administration of the two drugs are identical. Both drugs are administered orally. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy promulgated to implement Section 512(b)(2) of the FFD&C Act, in vivo bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Gentamicin Sulfate Pig Pump Oral Solution, is safe and effective for its labeled indications when used under its proposed conditions of use.

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.