Approval Date: November 13, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-137

B. Sponsor

Phoenix Pharmaceutical, Inc.
4621 Easton Road
P.O. Box 6457
Fairleigh Station St. Joseph, MO 64506-0457

C. Proprietary Name

Gentamicin Sulfate Solution

D. Established Name

gentamicin sulfate solution

E. Dispensing Status

Rx

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). For certain dosage forms, the Agency may grant a waiver from conducting an *in vivo* bioequivalence study (61 FR 26182, May 24, 1996; Bioequivalence Guidance). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Phoenix Pharmaceutical, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study with Gentamicin Sulfate Solution. The generic and pioneer products are solutions with the same concentrations of the active ingredient, and no differences in the inactive ingredients which may affect bioavailability of the active ingredient.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption:
Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. This drug is labeled for use in horses not intended for food.

Human Safety Relative to Possession, Handling and Administration:
Labeling contains adequate caution/warning statements.

IV. 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.

Safety and effectiveness for this generic animal drug, Gentamicin Sulfate Solution (gentamicin sulfate, 100 mg/mL), were established by demonstration of chemical equivalence to the pioneer product, Schering-Plough Animal Health Corporation's Gentocin® Solution (gentamicin sulfate, 100 mg/mL, NADA 046-724).

This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered by intrauterine infusion. The generic and pioneer products are solutions with the same concentrations of the active ingredient, and no differences in the inactive ingredients which may affect bioavailability of the active ingredient. Both products have the same pH. Therefore, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Gentamicin Sulfate 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.