Approval Date: August 4, 1995

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-023

B. Sponsor

Fermenta Animal Health Company
10150 North Executive Hills Blvd.
Kansas City, Missouri 64153

C. Proprietary Name

Gentamicin Sulfate Solution 100 mg/mL

D. Established Name

Gentamicin sulfate solution

E. Amount of Active Ingredient

Each mL contains gentamicin sulfate equivalent to 100 mg gentamicin base

F. Dispensing Status

Rx

G. Dosage Regimen

20 to 25 mL (2.0 to 2.5 grams) Gentamicin Sulfate Solution per day for 3 to 5 days during estrus

H. Route of Administration

Intrauterine infusion

I. Species/Class

Equine

J. Indication

For the control of bacterial infections of the uterus (metritis) in horses, and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

K. Pioneer Product

Gentocin® Solution (gentamicin sulfate, 100 mg/mL), NADA 046-724, Schering-Plough Animal Health Corporation

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). For certain dosage forms, the Agency grants a waiver conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter). 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 upon the formulation characteristics of the generic product, Fermenta Animal Health Company was granted a waiver November 19, 1990, (photocopy attached) from conducting an *in vivo* bioequivalence study with Gentamicin Sulfate Solution 100 mg/mL. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations 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 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 both solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, in compliance with FDA policy promulgated to implement 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 100 mg/mL 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.