

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-037

B. Sponsor

AgriLabs, Ltd.
P.O. Box 3103
St. Joseph, MO 64503

C. Proprietary Name

Gentamicin Sulfate Solution

D. Established Name

gentamicin 100 mg/mL solution

E. Dosage Form

Solution

F. Amount of Active Ingredient

Each mL contains gentamicin sulfate equivalent to 100 mg gentamicin base

G. How Supplied

100 mL multiple dose vials

H. Dispensing Status

Rx

I. Dosage Regimen

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

J. Route of Administration

Uterine infusion

K. Species/Class

Horses

L. Indication

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

M. Pioneer Product

Gentocin Solution (gentamicin sulfate, 100 mg/mL), NADA 046-724 by 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). New target animal safety data and drug effectiveness data, were not required for approval of this ANADA. This ANADA relies on the target animal safety and drug effectiveness data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. Bioequivalence is usually demonstrated through a clinical end-point study.

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, AgriLabs, Ltd. was granted a waiver from conducting an *in vivo* bioequivalence study for gentamicin sulfate solution. The generic and pioneer products are solutions with the same active and inactive ingredients. The generic and pioneer products also contain the same concentration of active ingredient. This ANADA was granted a waiver January 3, 1990 (see attachment).

III. HUMAN FOOD SAFETY

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this ANADA. This drug is labeled for use in horses not intended for food.

IV. AGENCY CONCLUSIONS

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that gentamicin sulfate solution, when used under its 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.