

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-115

B. Sponsor

Macleod Pharmaceuticals, Inc.
2600 Canton Court
Fort Collins, CO 80525

C. Proprietary Name

Gentamex™ 100

D. Established Name

Gentamicin sulfate 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 to 2.5 gram) Gentamex 100 per day for 3 to 5 days during estrus

J. Route of Administration

Intrauterine infusion

K. Species/Class

Equine

L. 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.

M. Reference Listed New Animal Drug

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). For certain dosage forms, the Agency may grant a waiver from 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 on the formulation characteristics of the generic product, Macleod Pharmaceuticals was granted a waiver November 5, 1990 (photocopy attached) from conducting an *in vivo* bioequivalence study with Gentamex 100. 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, Gentamex 100 (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 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 Gentamex 100 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. 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.

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