

Approval Date: March 14, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-178

B. Sponsor

Phoenix Scientific, Inc.
P.O. Box 6457
St. Joseph, MO 64506-0457

C. Proprietary Name

Amikacin Sulfate Injection

D. Established Name

amikacin sulfate

E. Dosage Form

solution

F. Amount of Active Ingredient

Each mL contains 50 mg of amikacin (base)

G. How Supplied

50 mL multiple dose vials

H. Dispensing Status

Rx

I. Route of Administration

Subcutaneous or Intramuscular Injection

J. Species/Class

Canine

K. Indication

For treatment of the following conditions in dogs: Genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* sp.

Skin and soft tissue infections caused by susceptible strains of *Pseudomonas* sp. and *Escherichia coli*.

L. Pioneer

Amiglyde-V® Injection (Amikacin Sulfate 50 mg/mL) manufactured by Fort Dodge Laboratories, Inc. (NADA 127-892)

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 in vivo bioequivalence testing, the bioequivalence of the generic product to the pioneer product is based on the demonstrated chemical equivalence to the pioneer product.

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver April 13, 1994, from conducting an in vivo bioequivalence study with Amikacin Sulfate Injection. The generic product is administered as a solution, contains the same active ingredient in the same concentration, is a subcutaneous or intramuscular dosage form as is the pioneer product, and contains the same inactive ingredients.

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 dogs only and should not be administered to food-producing animals.

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.

Bioequivalence of this generic animal drug, Amikacin Sulfate Injection (50 mg/mL), to the pioneer product were established by demonstration of chemical equivalence to the pioneer product, Fort Dodge's Amiglyde-V® Injection (NADA 127-892).

This generic product and the pioneer product have identical labeling indications for the 50 mL vial for use in dogs. The route and method of administration of the two drugs are identical. Both drugs are administered by injection. 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, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no in vivo bioequivalency studies were necessary or required.

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