Approval Date: September 11, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-061

B. Sponsor

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

C. Proprietary Name

(to be established)

D. Established Name

flunixin meglumine

E. Amount of Active Ingredient

Each mL contains 50 mg flunixin base

F. Dispensing Status

Rx

G. Dosage Regimen

The recommended dose is 0.5 mg per pound (1 mL/100 lbs.) of body weight once daily for up to five days.

H. Route of Administration

Intravenous or intramuscular injection

I. Species/Class

Equine

J. Indication

"Tradename" (flunixin meglumine) Solution is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in horses. It is also recommended for the alleviation of visceral pain associated with colic in horses

K. Reference Listed New Animal Drug

Banamine® (flunixin meglumine), manufactured by Schering-Plough Corporation (NADA 101-479).

II. TARGET ANIMAL SAFETY AND 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 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, AgriLabs was granted a waiver January 3, 1990 from conducting an in vivo bioequivalence study with Banamine®. 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, "trade name" (flunixin meglumine, 50 mg/mL), were established by demonstration of chemical equivalence to the pioneer product, Schering-Plough Corporation's Banamine® (flunixin meglumine, 50 mg/mL, NADA 101-479).

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 intravenous or intramuscular injection and repeated for up to five days. 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 flunixin meglumine 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.