Approval letter dated: Nov 1 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

ANADA 200-124

FLUXININ MEGLUMINE INJECTION

For the control of pyrexia associated with bovine respiratory disease and endotoxemia. Flunixin Meglumine Injection is also indicated for the control of inflammation in endotoxemia

Sponsored by:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503-0457

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. Generic Name:	flunixin meglumine injection
b. Trade Name:	FLUNIXIN MEGLUMINE INJECTION
c. Dosage Form:	Injectable Solution
d. How Supplied:	100 &250 ml vials
e. How Dispensed:	Rx
f. Amount of Active Ingredients:	50 mg/mL
g. Route of Administration:	Intravenous (Horses & Cattle) Intramuscular (Horses)
h. Species:	Horses and cattle (new)
i. Pioneer Product	BANAMINE® Injectable Solution NADA 101-479, Schering-Plough

Effect of Supplement: The supplement provides revised labeling with the addition of a new species, cattle, to the previously approved generic product for horses only.

2. 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). Phoenix Scientific, Inc. is supplementing their ANADA for the addition of cattle claims.

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on April 15, 1992, from conducting an *in vivo* bioequivalence study with flunixin meglumine solution. The generic product was approved on September 25, 1995, for use in horses only.

The three-year exclusivity period for the cattle claims granted to the pioneer product ended on May 5, 2001. Phoenix Scientific is supplementing their approved generic product for the addition of the cattle claims. No new data was required for the addition of the cattle claims.

3. HUMAN FOOD SAFETY

The acceptable daily intake (ADI), tolerance, target tissue, and withdrawal period are the same for the pioneer and generic products:

21 CFR 556.286: ADI is 0.72 micrograms/kg/day. A tolerance is established for parent flunixin free acid of 0.125 ppm in liver (target tissue) and 0.025 ppm in cattle muscle.

Withdrawal: 4 days

4. AGENCY CONCLUSION:

This is a Supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act. The Supplement provides for the addition of cattle claims to the previously approved horse claims. The exclusivity period granted to the pioneer for cattle claims ended on May 5, 2001.

Bioequivalence of this generic animal drug, FLUNIXIN MEGLUMINE INJECTION (50 mg/mL), to the pioneer product, Schering Plough's BANAMINE® Injectable Solution (NADA 101-479), was established by demonstration of chemical equivalence. The original generic animal drug was approved on September 25, 1995, for use in horses only.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)(v)(vii)), this is a Category II change providing for the addition of new therapeutic claims in cattle. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Attachment:

Generic facsimile labeling: 100 mL vial
250 mL vial
Package insert

Pioneer labeling: 100 mL vial
Package insert

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, Md 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6500.