Date of Approval: July 29, 2004

FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application

ANADA 200-061

Flunixin Meglumine Solution 50 mg/mL
(flunixin meglumine)

Injectable Solution for use in Horses, Beef Cattle, and Nonlactating Dairy Cattle

This supplement provides for the addition of a claim for intravenous use in beef cattle and nonlactating dairy cattle.

Sponsor:

Agri Laboratories, Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-061
b. Sponsor:	Agri Laboratories, Ltd. P.O. Box 3103 St. Joseph, MO 64503 Drug Labeler Code: 057561
c. Established Names:	Flunixin meglumine
d. Proprietary Name:	Flunixin Meglumine Solution
e. Dosage Form:	Sterile solution
f. How Supplied:	50 mL, 100 mL, and 250 mL multi-dose vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	50 mg/mL flunixin meglumine
i. Route of Administration:	For intravenous or intramuscular injection in horses and for intravenous injection in beef cattle and nonlactating dairy cattle
j. Species/Class:	Horses; beef cattle; nonlactating dairy cattle
k. Recommended Dosage:	Horse: The recommended dose for musculoskeletal disorders is 0.5 mg per pound (1mL/100 lbs) of body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days. The recommended dose for the alleviation of pain associated with equine colic is 0.5 mg per pound of body weight. Intravenous administration is recommended for prompt relief Treatment may be repeated when signs of colic recur.

	Cattle: The recommended dose for cattle is 1.1 to 2.2 mg/kg (0.5 to 1 mg/lb; 1 to 2 mL per 100 lbs.) given by slow intravenous administration either once a day as a single dose or divided into two doses administered at 12-hour intervals for up to 3 days. The total daily dose should not exceed 2.2 mg/kg (1.0 mg/lb) of body weight. Avoid rapid intravenous administration of the drug.
l. Pharmacological Category:	Anti-inflammatory; Analgesic
m. Indications:	Horse: Flunixin Meglumine is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse. Cattle: Flunixin Meglumine is indicated for the control of pyrexia associated with bovine respiratory disease and endotoxemia. Flunixin Meglumine is also indicated for the control of inflammation in endotoxemia.
n. Pioneer Product:	BANAMINE Injectable Solution; flunixin meglumine; NADA 101-479; Schering-Plough Animal Health Corp.
o. Effect of Supplement:	This supplement provides for the addition of a claim for intravenous use in beef cattle and nonlactating dairy cattle to the labeling of the approved product Flunixin Meglumine Solution. The exclusivity period protecting this claim for the pioneer product expired on May 6, 2001.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

This approval does not affect this section of the summary. Refer to the Freedom of Information Summary of the original ANADA 200-061 E-0004 dated September 11, 1996, for more detail.

3. HUMAN SAFETY:

- **Tolerance:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance is established for residues of parent flunixin free acid of 0.125 part per million (ppm) in cattle liver (target tissue) and 0.025 ppm in cattle muscle under 21 CFR 556.286. The acceptable daily intake for total residues of flunixin is 0.72 micrograms per kilogram of body weight per day (21 CFR 556.286).

- **Withdrawal Time:**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. For this reason, a withdrawal period of 4 days has been established for Flunixin Meglumine Solution (flunixin meglumine) in beef cattle and nonlactating dairy cattle (21 CFR 522.970).

- **Regulatory Method for Residues:**
  The determinative procedure for the determination of flunixin residues in bovine liver is a high performance liquid chromatography (HPLC) method. The confirmatory procedure for the determination of flunixin residues in bovine liver utilizes liquid chromatography/ mass spectrometry/mass spectrometry (LC/MS/MS) methodology.

  The validated methods are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Flunixin Meglumine Solution for use in horses, beef cattle, and non-lactating dairy cattle, when used under the proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling: Flunixin Meglumine Solution (ANADA 200-061)
Labels for 50 mL, 100 mL, and 250 mL multi-dose vials
Package Insert

Pioneer Labeling: BANAMINE Injectable Solution (NADA 101-479)
Labels for 50 mL, 100 mL, and 250 mL multi-dose vials
Package Insert