Date of Approval: November 17, 2003

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-308

Flunixin Injection

(flunixin meglumine)

50 mg/mL Injection

Cattle, Horses

It is indicated 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. In cattle, it is indicated for the control of pyrexia associated with bovine respiratory disease and endotoxemia. Flunixin Injection is also indicated for control of inflammation in endotoxemia.

Sponsored by:
Norbrook Laboratories Ltd.
Stations Works, Newry BT35 6JP,
Northern Ireland

FREEDOM OF INFORMATION SUMMARY

1. General Information:

a. File Number:	ANADA 200-308
b. Sponsor:	Norbrook Laboratories Ltd. Stations Works, Newry BT35 6JP, Northern Ireland Drug Labeler Code: 055529
c. Established Name:	Flunixin meglumine
d. Proprietary Name:	Flunixin Injection (50 mg/mL)
e. Dosage Form:	Injectable
f. How Supplied:	50, 100, 250 mL vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL contains flunixin meglumine equivalent to 50 mg of flunixin.
i. Route of Administration:	Intramuscularly or intravenously for horses; Intravenously for cattle
j. Species/Class:	Horses, beef cattle, and nonlactating dairy cattle
k. Recommended Dosage:	Horses: 0.5 mg/lb (1 mL/100 lbs) bodyweight once daily. Treatment may be repeated for up to five days. Cattle: 1.1 to 2.2 mg/kg (0.5 to 1 mg/lb; 1 to 2 mL per 100 lbs) bodyweight given by slow intravenous administration either once daily or divided into two doses administered at 12 hour intervals up to 3 days. The total daily dose should not exceed 2.2 mg/kg (1.0 mg/lb) of body weight.
l. Pharmacological Category:	Anti-inflammatory, anti-pyretic
m. Indications:	It is indicated 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. In cattle, it is indicated for the control of pyrexia associated with bovine respiratory disease and endotoxemia. Flunixin Injection is also indicated for control of inflammation in endotoxemia.

n. Pioneer Product: BANAMINE Injectable Solution (flunixin meglumine); NADA 101-479; Schering Plough Animal Health

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 (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2002).

Based on the formulation characteristics of the generic product, Norbrook Laboratories Limited was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Flunixin Injection (flunixin meglumine). The generic product is administered as an injectable solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, BANAMINE Injectable Solution (flunixin meglumine), the subject of Schering-Plough Animal Health, NADA 101-479, was approved on August 2, 1977.

3. HUMAN SAFETY:

· **Tolerance for Residues:**
The tolerance established for the pioneer product applies to the generic product.

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 are established under 21 CFR 556.286. The ADI for total residues of flunixin is 0.72 micrograms per kilogram of body weight per day.

· **Withdrawal Times:**
Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer.

Cattle: Do not slaughter for food use within 4 days of last treatment. Not for use in lactating or dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

Horses: Not for use in horses intended for food.

· **Regulatory Method for Residues:**
The determinative and confirmatory methods have been validated satisfactorily by FDA and USDA laboratories. The validated regulatory analytical methods for the detection of residues of flunixin meglumine are filed in the Food Additives Manual on display in FDA's Freedom of Information Public Room (Room 12A-30, 5600 Fisher's Lane, Rockville, MD 20857).

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 Injection (50 mg/mL), when used under its 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:

Pioneer Labeling for NADA 101-479:
BANAMINE Injectable Solution- 50, 100, and 250 mL vial size, insert and box

Generic Labeling for ANADA 200-308
Flunixin Injection-100 mL vial, insert and box