Date of Approval: June 22, 2009

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-476

Flunixin Injection -S
(flunixin meglumine)

Injectable Solution

Swine

Indications: Flunixin Injection-S is indicated for the control of pyrexia associated with swine respiratory disease

Sponsored by:

Norbrook Laboratories, Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-476
b. Sponsor:	Norbrook Laboratories, Ltd. Station Works Newry BT35 6JP Northern Ireland Drug Labeler Code: 055529 U.S. Agent: Dr. Bill Zollers Norbrook, Inc. 9733 Loiret Blvd. Lenexa, KS 66219
c. Established Name:	Flunixin meglumine
d. Proprietary Name:	Flunixin Injection -S
e. Dosage Form:	Injectable solution
f. How Supplied:	100 and 250 mL multiple dose vials
g. How Dispensed:	Rx
h. Amount of Active Ingredient:	Each mL contains flunixin meglumine equivalent to 50 mg of flunixin.
i. Route of Administration:	Intramuscular injection.
j. Species/Class:	Swine
k. Recommended Dosage:	The recommended dose for swine is 2.2 mg/kg (1 mg/lb; 2 mL per 100 lbs) body weight given by a single intramuscular administration. The injection should be given only in the neck musculature with a maximum of 10 mL per site.
l. Pharmacological Category:	Anti-inflammatory, anti-pyretic

m. Indications:	Flunixin Injection -S is indicated for the control of pyrexia associated with swine respiratory disease
n. Pioneer Product:	BANAMINE-S; flunixin meglumine; NADA 101-479; Schering-Plough Animal Health Corp.

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 effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that 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 the requirement of an in vivo bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Norbrook Laboratories, Ltd. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Flunixin (flunixin meglumine) Injection -S. The generic product is administered as 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-S (flunixin meglumine) the subject of Schering-Plough Animal Health Corp., NADA 101-479, was approved for use in horses on August 2, 1977; for beef and non-lactating dairy cattle on May 6, 1998; and swine on November 1, 2005.

3. HUMAN SAFETY:

- **Tolerances for Residues:**

  The tolerance established for the pioneer product applies to the generic product. A tolerance of 30 parts per billion (ppb) is established for flunixin free acid residues (the marker residue) in the liver (the target tissue) of swine, and 25 ppb in the muscle, under 21 CFR 556.286.

- **Withdrawal Times:**

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

  The withdrawal time is 12 days.

- **Regulatory Method for Residues:**

  The validated regulatory method for the determination and confirmation of residues of flunixin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Flunixin Injection -S, 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:

Generic Labeling for ANADA 200-476
Flunixin Injection -S - 100 mL and 250 mL vial labels; package insert; and carton labels

Pioneer Labeling for NADA 101-479:
BANAMINE-S - 100 mL vial label, package insert, and carton label