Date of Approval: March 1, 2010

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-489

FLUNAZINE-S
(flunixin meglumine)
Injectable Solution

Swine

For the control of pyrexia associated with swine respiratory disease

Sponsored by:

Cross Vetpharm Group, Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-489
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd. Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623 U.S. Agent: Linda M. Duple Director, North American Regulatory Affairs Bimeda, Inc. 2836 Dolliver Park Avenue Lehigh, IA 50557
c. Established Name:	Flunixin meglumine
d. Proprietary Name:	FLUNAZINE-S
e. Dosage Form:	Injectable solution
f. How Supplied:	100 mL multiple dose vial
g. How Dispensed:	Rx
h. Amount of Active Ingredient:	Each milliliter 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:	FLUNAZINE-S Injectable Solution is indicated for the control of pyrexia associated with swine respiratory disease.
n. Pioneer Product:	BANAMINE-S Injectable Solution; flunixin meglumine; NADA 101-479; Intervet, Inc.

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 Paten 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 date (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, Cross VetPharm Group Ltd. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product FLUNAZINE-S (flunixin meglumine) Injectable Solution. The generic product is administered as an intramuscular injection, 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) Injectable Solution, the subject of Schering-Plough Animal Health Corp., NADA 101-479, was approved for use in swine on November 1, 2005.

3. HUMAN SAFETY:

The following are assigned to this product for swine:

- **Tolerances for Residues:**
  The tolerances established for the pioneer product apply to the generic product. A tolerance of 30 parts per billion (ppb) is established for flunixin free acid residues (the marker residue) in the uncooked edible tissues of the liver (the target tissue), and 25 ppb in the muscle, under 21 CFR 556.286. The acceptable daily intake (ADI) for total residues of flunixin meglumine 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 product.

  A withdrawal period of 12 days has been established for flunixin meglumine in swine.

- **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 FLUNAZINE-S Injectable Solution, 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 200-489
FLUNAZINE-S Injectable Solution- 100 mL vial labels and package outsert

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