Date of Approval: December 18, 2001

FREEDOM OF INFORMATION SUMMARY

ANADA 200-293

Indication for use: It is used for the treatment of edema associated with cardiac insufficiency, acute noninflammatory tissue edema, physiological parturient edema of the mammary gland and associated structures.

Sponsored by:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number	200-293
	JINAD 10-179
Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, MO 64503
	21 CFR 510.600: Labeler Code 059130
Established Name:	Furosemide Injection 5 %
Trade/Proprietary Name:	Furosemide Injection 5 %
Dosage Form:	Injectable
How Supplied:	50 & 100 mL multidose vials
How Dispensed:	Rx
Amount of Active Ingredients:	Each mL contains 50 mg of furosemide as diethanolamine
Route of Administration:	Intramuscularly or intravenously
Species:	Cattle, horses, dogs and cats
Labeled Dosage	Dog and cat-1/4 to ½ mL/10 lbs BID or SID Horse-5 to 10 mL BID or SID Cattle-5 mL BID or 10 mL SID
Indications for Use:	Diuretic-saluretic for prompt relief of edema
Pharmacological Category:	Diuretic-saluretic

Pioneer Product: Lasix® 5% Injection manufactured by Intervet, Inc. (NADA 034-478)

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). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on September 29, 1997, from conducting an *in vivo* bioequivalence study for Furosemide Injection 5 %. The generic and pioneer products contain the same active and inactive ingredients and are injectable solutions.

3. HUMAN FOOD SAFETY:

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for furosemide is established under 21 CFR 522.1010- 48 hours in cattle. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food.

Currently, there is no tolerance listed for the chemical component 'furosemide' in the Code of Federal Register(section 21 CFR 556).

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the Act and demonstrates that Furosemide Injection 5 % is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

50 mL vial

Generic Labeling:

Package Insert

50 mL & 100 mL vials

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) 827-6567.