Date of Approval: November 18, 2004

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-382

Furosemide Syrup 1%
(Furosemide)

Oral Diuretic, Saluretic

A diuretic-saluretic for oral use alone or in combination with Furosemide Injection in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

Sponsored by:

Phoenix Scientific, Inc.
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-382
b. Sponsor:	Phoenix Scientific, Inc. 3915 South 48th St. Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Furosemide
d. Proprietary Name:	Furosemide Syrup 1%
e. Dosage Form:	Syrup
f. How Supplied:	60 mL bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	10 mg of furosemide per mL
i. Route of Administration:	Oral
j. Species/Class:	Dogs
k. Recommended Dosage:	Dog: 1 to 2 mL (10-20 mg) Furosemide Syrup 1% for each 10 lb. body weight. Administer once or twice daily at 6 to 8 hour intervals. Dispense in this container with calibrated safety dropper. Use dropper to measure and administer Furosemide Syrup 1%.
l. Pharmacological Category:	Diuretic
m. Indications:	A diuretic-saluretic for oral use alone or in combination with Furosemide Injection in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.
n. Pioneer Product:	LASIX (Furosemide) Syrup 1%; NADA 102-380; 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 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 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 the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Furosemide Syrup 1%. The generic product is administered as an oral solution and contains the same active ingredient in the same concentration and dosage form as the pioneer product. The generic product contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product LASIX (Furosemide) Syrup 1%; the subject of Intervet, Inc. NADA 102-380, was approved on March 17, 1998.

3. HUMAN SAFETY:

This drug is indicated only for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human warning statements are provided on the product labeling as follows: **"Keep this and all medication out of the reach of children.",** and **"FOR USE IN DOGS ONLY."**

4. AGENCY CONCLUSIONS:

This ANADA filed 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 Furosemide Syrup 1%, 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 200-382:
AMTECH Furosemide Syrup 1%, 60 mL label with calibrated safety dropper
AMTECH Furosemide Syrup 1%, Package Insert
AMTECH Furosemide Syrup 1%, Carton Printing

Pioneer Labeling for NADA 102-380:
LASIX (Furosemide) Syrup 1%, 60 mL label with calibrated safety dropper
LASIX (Furosemide) Syrup 1%, Package Insert
LASIX (Furosemide) Syrup 1%, Carton Printing