Approval Date: November 21, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-435

RESPIRAM
doxapram hydrochloride

Indications for use: For dogs, cats and horses: To stimulate respirations during and after general anesthesia. To speed awakening and return of reflexes after anesthesia. For neonate dogs and cats: Initiate respirations following cesarean section or dystocia. To stimulate respirations following dystocia or cesarean section.

Sponsored by:

Modern Veterinary Therapeutics, LLC

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-435
b. Sponsor:	Modern Veterinary Therapeutics, LLC 18301 SW 86 Ave. Miami, FL 33157 Drug Labeler Code: 015914
c. Established Name:	Doxapram hydrochloride
d. Proprietary Name:	RESPIRAM
e. Dosage Form:	Sterile solution
f. How Supplied:	20 mL vial
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Doxapram hydrochloride 20 mg/mL
i. Route of Administration:	Intravenous, subcutaneous, sublingual or umbilical vein
j. Species/Class:	Dogs, cats and horses
k. Recommended Dosage:	Dogs and cats: 2.5 mg/lb intravenous Horses: 0.25 mg/lb intravenous Neonate puppies: 1-5 mg subcutaneous, sublingual or umbilical vein Neonate kittens: 1-2 mg subcutaneous or sublingual
l. Pharmacological Category:	CNS stimulant
m. Indications:	For dogs, cats and horses: To stimulate respirations during and after general anesthesia. To speed awakening and return of reflexes after anesthesia. For neonate dogs and cats: Initiate respirations following cesarean section or dystocia. To stimulate respirations following dystocia or cesarean section.

n. Pioneer Product: DOPRAM–V Injectable; doxapram hydrochloride; NADA 034-879; Fort Dodge Animal Health, Division of Wyeth

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, Modern Veterinary Therapeutics, LLC was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product RESPIRAM (doxapram hydrochloride solution). The generic product is administered as a sterile solution, contains the same active ingredients 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, DOPRAM-V solution (doxapram hydrochloride), the subject of Fort Dodge Animal Health, Division of Wyeth, NADA 034-879, was approved on May 2, 1967.

3. HUMAN SAFETY:

This drug is intended for use in dogs, cats and horses, 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.

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 the injectable product RESPIRAM, 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 follows:

Generic Labeling for ANADA 200-435:
RESPIRAM – Container Label, Box Label- 20 mL vial
Package insert

Pioneer Labeling for NADA 034-879:
DOPRAM V - Container Label, Box Label – 20 mL vial
Package insert