

Date of Approval: October 2, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-365

Glycopyrrolate Injection 0.2 mg/mL
(glycopyrrolate)

Sterile Solution

For use in dogs and cats

A preanesthetic anticholinergic agent in dogs and cats.

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Sponsored by:

IVX Animal Health, Inc.

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

- a. File Number: ANADA 200-365
- b. Sponsor: IVX Animal Health, Inc.
3915 South 48th Street Ter.
St. Joseph, MO 64503

Drug Labeler Code: 059130
- c. Established Name: Glycopyrrolate, USP
- d. Proprietary Name: Glycopyrrolate Injectable 0.2 mg/mL
- e. Dosage Form: Sterile solution
- f. How Supplied: 20 cc vial
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: 0.2 mg/mL
- i. Route of Administration: Intravenous, intramuscular, or subcutaneous in dogs; intramuscular in cats
- j. Species/Class: Dogs and cats
- k. Recommended Dosage: Dogs: 5 micrograms/lb body weight (0.25 mL per 10 lbs body weight).

Cats: 5 micrograms / lb body weight (0.25 mL per 10 lbs body weight). For maximum anticholinergic effect administer 15 minutes prior to anesthetic administration in cats.
- l. Pharmacological Category: Preanesthetic, anticholinergic
- m. Indications: As a preanesthetic anticholinergic agent in dogs and cats
- n. Pioneer Product: ROBINUL-V; glycopyrrolate; NADA 101-777; 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 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 Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Glycopyrrolate (glycopyrrolate) Injectable 0.2 mg/mL. The generic product is administered as an injectable sterile solution, contains similar 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 ROBINUL-V (glycopyrrolate), the subject of Fort Dodge Animal Health, Division of Wyeth, NADA 101-777, was approved on June 3, 1977.

3. HUMAN SAFETY:

This drug is intended for use in dogs and cats 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 NADA.

Human Warnings are provided on the product label as follows: Not applicable

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 Glycopyrrolate Injectable 0.2 mg/mL, 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 200-365:

Glycopyrrolate Injectable 0.2 mg/mL
20 mL vial label
Label outsert
Shipping label

Pioneer Labeling for NADA 101-777:

ROBINUL-V
20 mL vial label
Package Insert
Carton label