Date of Approval: March 25, 2003

FREEDOM OF INFORMATION (FOI) SUMMARY

Acepromazine Maleate Injection
10 mg/mL

Tranquilizer for use in dogs, cats, and horses

ANADA 200-319

Phoenix Scientific, Inc.

3915 South 48th Street Terrace

St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. ANADA Number: 200-319

b. SPONSOR: Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503

Drug Labeler Code: 059130

c. Established Name: Acepromazine Maleate Injection

d. Proprietary Name: Acepromazine Maleate Injection

e. Dosage Form: Injection (solution)

f. How Supplied: 50 mL glass bottles

g. How Dispensed: ℞

h. Amount of Active Ingredients: 10 mg acepromazine maleate/mL

i. Route of Administration: Intravenous, Intramuscular, or Subcutaneous Injection

j. Species: Canine, Feline and Equine

k. Labeled Dosage:

The dosage should be individualized, depending upon the degree of tranquilization required. As a general rule, the dosage requirement in mg/lb of body weight decreases as the weight of the animal increases. Acepromazine Maleate Injection may be given intravenously, intramuscularly or subcutaneously. The following schedule may be used as a guide to IV, IM or SC injections:

Dogs: 0.25-0.5 mg/lb of body weight
Cats: 0.5-1 mg/lb of body weight
Horses: 2-4 mg/100lb of body weight
IV doses should be administered slowly, and a period of at least 15 minutes should be allowed for the drug to take full effect.

l. Pharmacological Category: Anesthetic

m. Indications For Use: **Dogs and Cats**: Acepromazine Maleate Injection can be used as an aid in controlling intractable animals during examination, treatment, grooming, x-ray and minor surgical procedures; to alleviate itching as a result of skin irritation; as an antiemetic to control vomiting associated with motion sickness.

Acepromazine Maleate Injection is particularly useful as a preanesthetic agent (1) to enhance and prolong the effects of barbiturates, thus reducing the requirements for general anesthesia; (2) as an adjunct to surgery under local anesthesia.

Horses: Acepromazine Maleate Injection can be used as an aid in controlling fractious animals during examination, treatment, loading and transportation. Particularly useful when used in conjunction with local anesthesia for firing, castration, neurectomy, removal of skin tumors, ocular surgery and applying casts.

n. Pioneer Product PromAce® Injectable NADA 015-030
(Fort Dodge Animal Health, Inc.)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVIENESS

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.

Ordinarily, the ANADA sponsor shows 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 end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement of 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 from conducting an *in vivo* bioequivalence study for Acepromazine Maleate Injection on October 20, 1997 (JINAD 010-181 R0000). The generic and pioneer products contain the same active and inactive ingredients in the same concentrations.

3. HUMAN SAFETY:

None required as Acepromazine Maleate Injection is labeled for use in dogs, cats, and horses. The labeling also contains the statement, "Warning: Not for use in animals intended for food".

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)(2) of the Federal Food, Drug, and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the act and demonstrates that Acepromazine Maleate Injection, when used under its proposed conditions of use, is safe and effective for the labeled indications.

5. Attachments:

1. Generic Labeling: Facsimile package labeling for generic product, 50 ml bottle, and package insert.
2. Pioneer Labeling: Bottle Label, Package Insert, Printed Chipboard