Date of Approval: April 14, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-361

Acepromazine Maleate Injection
(acepromazine maleate)

Tranquilizer

For use as an aid in tranquilization and as a preanesthetic agent
in dogs, cats, and horses.

Sponsored by:

Boehringer Ingelheim Vetmedica, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-361
b. Sponsor:	Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Highway St. Joseph, MO 64506-2002 Drug Labeler Code: 000010
c. Established Name:	Acepromazine maleate
d. Proprietary Name:	Acepromazine Maleate Injection
e. Dosage Form:	Sterile solution
f. How Supplied:	50 mL multidose vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	10 mg acepromazine maleate per mL of sterile finished product
i. Route of Administration:	Intravenous, intramuscular or subcutaneous injection
j. Species/Class:	Dogs, cats, and horses
k. Recommended 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. The following schedule may be used as a guide to intravenous, intramuscular, or subcutaneous injection: Dogs – 0.25 mg-0.5 mg/lb of body weight Cats – 0.5-1 mg/lb of body weight Horses – 2-4 mg/100 lb of body weight Intravenous 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:	Tranquilizer
m. Indications:	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; acepromazine maleate; NADA 015-030; 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 Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Boehringer Ingelheim Vetmedica, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Acepromazine Maleate Injection. The generic product is administered as an intravenous, intramuscular or subcutaneous injection, contains the same active ingredient 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 PROMACE Injectable (acepromazine maleate), the subject of Fort Dodge Animal Health, Division of Wyeth, NADA 015-030, was approved on April 8, 1964.

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 Acepromazine Maleate Injection, 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 200-361:
Acepromazine Maleate Injection; vial labels and package insert

Pioneer Labeling for NADA 015-030:
PROMACE Injectable; vial labels and package insert