Date of Approval: February 3, 2005

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-280

Euthanasia-III Solution (Euthanasia Solution)

For canine euthanasia only

Euthanasia-III Solution (Euthanasia Solution) is for use in dogs for humane, painless, and rapid euthanasia.

Sponsored by:

Med-Pharmex, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-280
b. Sponsor:	Med-Pharmex, Inc. 2727 Thompson Creek Rd. Pomona, CA 91767 Drug Labeler Code: 051259-1861
c. Established Name:	Pentobarbital sodium and phenytoin sodium
d. Proprietary Name:	Euthanasia-III Solution
e. Dosage Form:	Solution
f. How Supplied:	100 mL Multiple-Dose Vial
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL contains: 390 mg pentobarbital sodium (barbituric acid derivative), 50 mg phenytoin sodium.
i. Route of Administration:	Intravenous or intracardiac
j. Species/Class:	Dogs
k. Recommended Dosage:	1 mL for each 10 pounds of body weight.
l. Pharmacological Category:	Pentobarbital sodium – anesthetic Phenytoin sodium – anticonvulsant
m. Indications:	For use in dogs for humane, painless, and rapid euthanasia.
n. Pioneer Product:	BEUTHANASIA-D Special (Euthanasia Solution); pentobarbital sodium and phenytoin sodium; NADA 119-807; Schering-Plough Animal Health Corp.

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, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Euthanasia-III (Euthanasia Solution)(pentobarbital sodium and phenytoin sodium). The generic product is administered as a nonsterile injectable 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 ingredients. The pioneer product BEUTHANASIA-D (Euthanasia Solution) (pentobarbital sodium and phenytoin sodium), the subject of Schering-Plough Animal Health Corp.'s, NADA 119-807, was approved on April 4, 1981.

3. HUMAN SAFETY:

This drug is intended 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 Warnings are provided on the product label as follows: "HUMAN WARNING Caution should be exercised to avoid contact of the drug with open wounds or accidental self-inflicted injections. Keep out of reach of children. If eye contact, flush eyes with water and seek medical attention. FOR DOGS ONLY."

4. AGENCY CONCLUSIONS:

This ANADA submitted 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 Euthanasia-III Solution (Euthanasia Solution), 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 200-280:
Euthanasia-III Solution
- 100 mL bottle label (will also be attached to white individual bottle carton)
- Package Insert

Pioneer Labeling for NADA 119-807:
BEUTHANASIA-D Special (Euthanasia Solution)
- 100 mL bottle label
- Package insert
- Individual carton label