Approval Date: February 24, 1994

# FREEDOM OF INFORMATION SUMMARY

## I. GENERAL INFORMATION

### A. File Number

ANADA 200-071

### B. Sponsor

Delmarva Laboratories, Incorporated
P.O. Box 525
Midlothian, VA 23113

### C. Proprietary Name

Euthasol™

### D. Established Name

pentobarbital sodium and phenytoin sodium

### E. Dosage Form

Non-sterile parenteral solution

### F. Amount of Active Ingredient

Each mL contains: 390 mg pentobarbital sodium (barbituric acid derivative) and 50 mg phenytoin sodium

### G. Amount of Inactive Ingredients

ethyl alcohol 10%, propylene glycol 18%, rhodamine B 0.003688 mg, benzyl alcohol (preservative) 2%, water for injection q.s. Sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

### H. How Supplied

Euthasol(TM) is available in 100 mL multiple dose vials

### I. Dispensing Status

Rx

### J. Route of Administration

Intravenous injection is preferred. Intracardiac injection may be made when intravenous injection is impractical, as in a very small dog, or in a comatose dog with impaired vascular functions. Good injection skill is necessary for intracardiac injection. The calculated dose should be given in a single bolus injection. For intravenous injection, a needle of sufficient gauge to insure intravenous placement of the entire dose should be used.

### K. Species/Class

Canine

### L. Indication

For use in dogs for humane, painless, and rapid euthanasia

### M. Labeled Dosage

1 mL for each 10 pounds of weight.

### N. Reference Listed New Animal Drug

Beuthanasia®-D Special (390 mg pentobarbital sodium (barbituric acid derivative) and 50 mg phenytoin sodium), manufactured for Schering Corporation (NADA 119-807)

## II. DRUG EFFECTIVENESS AND TARGET ANIMAL SAFETY

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 reside data) are not required for approval of an ANADA. An ANADA relies on the target animal safety drug effectiveness and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. 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 conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

## III. AGENCY CONCLUSIONS

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Euthasol™ (pentobarbital sodium and phenytoin sodium), when used under its proposed conditions of use, is safe and effective for its labeled indications.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.