

Date of Approval: February 7, 2020

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-614

Pentobarbital Sodium and Phenytoin Sodium
Injectable Solution
Dogs

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

Sponsored by:
Akorn Animal Health, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-614

B. Sponsor

Akorn Animal Health, Inc.,
1925 West Field Ct.,
Suite 300,
Lake Forest, IL 60045

Drug Labeler Code: 059399

C. Proprietary Name

Pentobarbital Sodium and Phenytoin Sodium

D. Drug Product Established Name

pentobarbital sodium and phenytoin sodium

E. Pharmacological Category

Barbiturate euthanasia solution

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

390 mg/mL pentobarbital sodium and 50 mg/mL phenytoin sodium

H. How Supplied

100 mL multi-dose vials in package of one

I. Dispensing Status

Rx

J. Dosage Regimen

1 mL for each 10 pounds of body weight

K. 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.

L. Species/Class

Dogs

M. Indications

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

N. Reference Listed New Animal Drug (RLNAD)

BEUTHANASIA®-D SPECIAL; pentobarbital sodium and phenytoin sodium; NADA 119-807; Intervet, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Akorn Animal Health, Inc. was granted a biowaiver for the generic product Pentobarbital Sodium and Phenytoin Sodium injectable solution. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is BEUTHANASIA®-D SPECIAL (pentobarbital sodium and phenytoin sodium) injectable solution, sponsored by Intervet, Inc., under NADA 119-807 and, was approved for use in dogs on April 24, 1981.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Pentobarbital Sodium and Phenytoin Sodium:

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.

V. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that Pentobarbital Sodium and Phenytoin Sodium when used according to the label, is safe and effective.