

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

ANADA 200-028

#### B. Sponsor

Lambert-Kay  
Division of Carter-Wallace, Inc.  
Half Acre Road  
P.O. Box 1001  
Cranbury, New Jersey 08512-0181

#### C. Proprietary Name

Evict® DS and Lassie® DS Liquid Wormer plus Vet's Own™ DS Canine Anthelmintic Suspension

#### D. Established Name

pyrantel pamoate

#### E. Pharmacological Category

Anthelmintic

#### F. Amount of Active Ingredient

Each mL contains 4.54 mg of pyrantel base as pyrantel pamoate.

#### G. Dispensing Status

OTC

#### H. Route of Administration

Oral with or without food

#### I. Species/Class

Canine (puppies and dogs)

#### J. Indication

To prevent reinfection of *Toxacara canis* in puppies and adult dogs and in lactating bitches after whelping. For removal of large roundworms (*Toxacara canis* and *Toxacaris leonia*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies.

#### K. Pioneer Product

NENEX-2™, NADA 100-237, Pfizer Inc.

#### **L. Effect of Supplement**

To provide for a double strength pyrantel pamoate suspension.

### **II. TARGET ANIMAL SAFETY AND EFFECTIVENESS**

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).

For certain dosage forms, the agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990: fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based upon the formulation characteristics of the generic product, Lambert-Kay, Division of Carter-Wallace, Inc. was granted a waiver from conducting an in vivo bioequivalence study with pyrantel double strength. The generic and pioneer products are suspensions with the same active and similar inactive ingredients.

### **III. HUMAN FOOD SAFETY**

**Human Safety Relative to Food Consumption:** Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. The drug is to be labeled for use in dogs and puppies.

**Human Safety Relative to Possession, Handling and Administration:** Labeling contains adequate caution/warning statements

### **IV. AGENCY CONCLUSIONS**

This is an Abbreviated New Animal Drug Application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, pyrantel pamoate suspension, were established by demonstration of chemical equivalence to the pioneer product, Pfizer, Inc. Nemex-2™ (NADA 100-237).

This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are orally administered. The generic and pioneer products are both suspensions that contain the same active in the same concentration and similar inactive ingredients. Therefore, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or in vivo bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that pyrantel pamoate double strength oral suspension (EVICT® DS and LASSIE® DS Liquid Wormer plus VET'S OWN™ DS), when used under proposed conditions of use, are safe and effective for labeled indications.

#### **Generic Labeling:**

1. EVICT® DS:

- 2 oz. bottle and carton
  - 4 oz. bottle and carton
  - 8 oz. bottle and carton
  - 16 oz. bottle and package insert
2. LASSIE® DS:
    - 2 oz. bottle and carton
    - 4 oz. bottle, carton and package insert
  3. VET'S OWN™ DS:
    - 2 oz. bottle and carton
    - 4 oz. bottle and carton
    - 8 oz. bottle
    - 16 oz. bottle and package insert

**Pioneer Labeling:**

1. Nemex-2™: 2 oz. bottle, carton and package insert
2. D-Worm™ 120: package insert

Copies of applicable labels may be obtained by writing to the:  
Freedom of Information Office  
Center for Veterinary Medicine, FDA  
7500 Standish Place  
Rockville, MD 20855

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.