FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-028
Sponsor	LAMBERT KAY Division of CARTER-WALLACE, INC. P.O. Box 1418 Cranbury, New Jersey 08512-0187
Trade Name:	Evict®, Lassie®, Vet's Own™
Established Name:	pyrantel pamoate
Dosage Form:	Oral suspension
How Supplied:	Evict®: 2 oz. (60 mL), 4 oz. (118 mL), 8 oz. (237 mL), and 16 oz. (473 mL) bottles Lassie®: 2 oz. (60 mL) and 4 oz. (118 mL) bottles Vet's Own™: 2 oz. (60 mL), 4 oz. (118 mL), 8 oz. (237 mL), and 16 oz. (473 mL) bottles
How Dispensed:	OTC
Amount of Active Ingredients:	Each mL contains 2.27 mg of pyrantel base as pyrantel pamoate
Route of Administration:	Oral
Species:	Dogs
Labeled Dosage:	1 teaspoonful (5 mL) for each 5 pounds of body weight
Indications for Use:	To prevent reinfection of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping. For removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in dogs and puppies.
Pioneer Product:	Nemex™, NADA 100-237, Pfizer Inc.

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 (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 will not grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990). Bioequivalence of the generic and pioneer products can be demonstrated by a clinical end-point study. The ANADA relies on the target animal safety and drug effectiveness data in the pioneer's New Animal Drug Application (NADA).

EFFECTIVENESS:

The effectiveness of pyrantel pamoate oral suspension has been established by data contained in approved NADA 100-237. The following clinical end point and palatability studies establish the therapeutic bioequivalence of the generic Lambert Kay product to the pioneer Pfizer product.

I. Controlled Test (Anthelmintics)

1. Name and Address of Investigator:

Richard E. Bradley, D.V.M., Ph.D.
ANIMAL HEALTH ADVISORS
RR #1, Box 386
Alachua, Florida 32615

2. General Design of Study:

a. Purpose of Study: To demonstrate bioequivalence between Lambert Kay's formulation of pyrantel pamoate and Nemex™, Pfizer brand of pyrantel pamoate canine anthelmintic.

b. Test Animals: A total of 29 dogs of both sexes, mixed breeding and approximately six weeks of age, were enrolled in the study. The dogs were purchased from an essentially helminth-free environment, and showed no evidence of parasite ova on fecal flotation exams conducted on 3 consecutive days. There were 10 dogs receiving Lambert Kay's pyrantel pamoate (Group A), 10 dogs receiving Pfizer's Nemex (Group B), and 9 dogs without treatment as controls.

c. Establishment of Parasite Infestation: Dogs were artificially infected with embryonated *T. canis* ova, and with infective L_3 larvae of *A. caninum*. All animals were confirmed to have patent *T. canis* and *A. caninum* infections by fecal flotation egg counts conducted approximately 30 to 60 days after induction of infection. Fecal flotations for parasite ova were conducted on Days -11 and -6 relative to treatment day.

d. Route of Administration: The treatments were given orally one time only via disposable syringes directly into the oral cavity to assure appropriate dosing.

e. Dosage Used: Dose in study was 1 mL/lb. body weight, equivalent to 2.27 mg pyrantel base/lb. The test and pioneer drugs were provided in unlabeled, coded containers.

f. Pertinent Parameters Measured:

i. Animals were observed for clinical signs of toxicity between dosing and necropsy.

ii. All animals were necropsied 72 hours post-treatment and the intestinal tracts opened and examined for the presence of worms. All worms were collected, counted, and identified.

Efficacy was calculated by the following formula:

$$\frac{\text{Mean \# parasites in untreated controls} - \text{mean \# parasites in treated controls}}{\text{Mean \# parasites in untreated controls}} \times 100 = \% \text{ efficacy}$$

3. Results

Group	Treatment	No. of Dogs	Parasite	Total Worms Recovered	Percent Efficacy
A	Lambert Kay pyrantel	10	*T. canis*	1	98
			A. caninum	4	99
B	Pfizer Nemex	10	*T. canis*	0	100
			A. caninum	0	100
C	Untreated	9	*T. canis*	511	NA
			A. caninum	1508	NA

4. Conclusions: Based on the results of this controlled anthelmintic efficacy trial, Lambert Kay's pyrantel pamoate suspension is bioequivalent to the pioneer product, Pfizer's Nemex.

5. Adverse Reactions: It was noted that one female dog in Group A exhibited vomiting approximately 10 minutes after treatment, but the investigator attributed this to excitement due to handling the animal. The dog was retreated uneventfully the next day, and no other toxic signs were noted.

II. Palatability Test - 9005

1. Name and Address of Investigator:

Larry R. Cruthers, Ph.D.
Professional Laboratory and Research Services, Inc.

Route 1, Box 34A
Corapeake, North Carolina 27926

2. General Design of Study

   a. Purpose of Study: Determine if any differences in palatability exist between Lambert Kay experimental pyrantel pamoate and Pfizer's Nemex.

   b. Test Animals: A total of 20 adult dogs of both sexes and mixed breeding were used.

   c. Dosage Form: Oral suspension

   d. Route of Administration: The treatments were offered orally by placing into an empty food bowl. If there was reluctance to consume the drug, then the dose was mixed with a small quantity of canned dog food.

   e. Dosage Used: Dose in study was 1 mL/lb body weight equivalent to 2.27 mg pyrantel base/lb.

   f. Test Parameters: The study was conducted as a two-period crossover design. Initially 10 dogs received Pfizer's Nemex (Group A), while the remaining 10 dogs received Lambert Kay pyrantel pamoate (Group B). Treatments were reversed the following day.

      Time for consumption was recorded from the point when the medication was initially offered until medication was completely consumed. For those dogs which did not consume the medication directly, time was recorded from the presentation of treated canned dog food until the medicated food was completely consumed.

      All animals fully consumed either the free choice product or medicated canned food during the two day study.

3. Results:

Treatment	No. Dogs Offered	No. Dogs Consumed Directly	Average Consumption Time	No. Dogs Consumed With Food	Average Volume Consumed
Pfizer Nemex	20	14	15.7 secs	6	28.3 mL
LK Pyrantel	20	15	19.6 secs	5	28.3 mL

4. Conclusions: There was no clinically significant difference in palatability between the two product formulations.

5. Adverse Reactions: No adverse reactions were observed during this study.

ANIMAL SAFETY

The animal safety of pyrantel pamoate oral suspension has been adequately demonstrated previously by Pfizer's approved NADA 100-237.

3. HUMAN 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. This drug is labeled for use in non-food animals (dogs).

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that pyrantel pamoate oral suspension (Evict®, Lassie®, and Vet's Own™) is safe and effective for its labeled indications when used under its proposed conditions of use.