

ECO LLC
8209 Hollister Avenue
Las Vegas, NV 89131

2033 01 SEP -6 P2:26

August 31, 2001

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**CITIZEN PETITION
(ANADA SUITABILITY PETITION)**

ECO LLC hereby submits this petition under Section 512 (n) (3) of the Federal Food, Drug and Cosmetic Act to seek permission from the Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, to file an Abbreviated New Animal Drug Application (ANADA) which differs in dosage form from the innovator product.

A. Action requested

ECO LLC seeks permission to file an ANADA for a generic equivalent of the innovator product Heartgard 30® Chewables, NADA 140-886, Merial Ltd, which differs from the innovator product in dosage form. Ivermectin generic is a compressed chewable tablet whereas Heartgard 30® Chewables is an 'extruded' chewable tablet.

B. Statement of grounds

Under provisions of the Federal Food, Drug, and Cosmetic Act, Section 512 (n)

(3) If a person wants to submit an abbreviated application for a new animal drug--

- (A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or**
- (B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,**

such person shall submit a petition to the Secretary seeking permission to file such an application.

01P-0394

CPI

This ANADA Suitability Petition qualifies under the provisions of the Federal Food, Drug, and Cosmetic Act, Section 512 (n) (3) (A) in that permission is sought to change only the dosage form of an approved new animal drug. Ivermectin generic is a compressed chewable tablet whereas Heartgard 30® Chewables is an 'extruded' chewable tablet.

The active ingredient in the ivermectin generic chewable, ivermectin, will be the same as the innovator Heartgard 30® Chewable and will be included in the generic product at the same concentration and dosed at the same rate and frequency as the innovator:

- A. **DOSAGE FORM** Ivermectin is formulated in a palatable compressed chewable tablet. Three dosage strengths are available for dogs of different weight classes.
- B. **ROUTE OF ADMINISTRATION** The ivermectin generic chewable tablets are administered orally at monthly intervals during the mosquito (vector for *D. immitis*) season.
- C. **RECOMMENDED DOSAGES:** The ivermectin generic chewable tablets are administered once monthly and provide a minimum of 6 mcg ivermectin per kg of body weight (2.72 mcg/lb) when given as follows:

<u>Ivermectin</u>	<u>Dog Weight</u>
68 mcg	Up to 11 kg (25 lb.)
136 mcg	12 to 22 kg (26 to 50 lb.)
272 mcg	23 to 45 kg (51 to 100 lb.)

Dogs heavier than 45 kg (100 lb.) are administered the appropriate combination of these chewable tablets.

The labeling for the ivermectin generic chewable tablet will be identical to the pioneer Heartgard-30® Chewables labeling with the exception of substitution of ECO LLC's product name(to be determined) and company name and address.

The indications for use will include the indications for the original NADA 140-886 approved July 3, 1989:

INDICATIONS FOR USE:

For use in dogs to prevent canine heartworm disease. Ivermectin generic chewables (ivermectin) prevents heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for a month (30 days) after infection.

C. Environmental impact

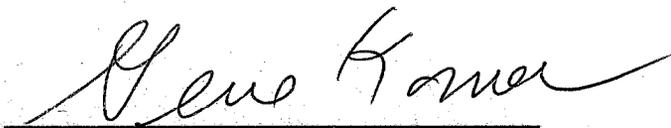
ECO LLC believes that this petition is subject to categorical exclusion under 21 CFR 25.24.

D. Economic impact

An economic impact analysis will be provided if requested after review of this petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Gene Komer, Ph.D., Consultant
2817 West County Road 54G
Fort Collins, CO 80524-1087

Ph.D.
County Road 54G
PO 80524-1087


UNITED STATES
POSTAL SERVICE
9261

AMOUNT
\$0.57

U.S. POSTAGE
PAID
LAPORTE, CO
80535
AUG 31, '01
00054360-02
20852



First Class Mail
First Class Mail

**Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852**

FIRST CLASS

FIRST CLASS

Gene Komer, Ph.D.
2817 West County Road 54G
Fort Collins, CO 80524-1087



UNITED STATES
POSTAL SERVICE

9261



AMOUNT

\$0.57

First Class Mail
First Class Mail

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852