ECO LLC
8209 Hollister Avenue
Las Vegas, NV 89131

August 28, 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® Plus, NADA 140-971, Merial Ltd, which differs from the innovator product in dosage form. Ivermectin/pyrantel generic is a compressed chewable tablet whereas Heartgard® Plus 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-0382

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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/pyrantel generic is a compressed chewable tablet whereas Heartgard® Plus is an 'extruded' chewable tablet.

The active ingredients in the ivermectin/pyrantel generic chewable, ivermectin and pyrantel (as the pamoate salt), will be the same as the innovator Heartgard® Plus 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 and pyrantel (as pamoate salt) are formulated in a palatable compressed chewable tablet. Three dosage strengths are available for dogs of different weight classes.**
B.	**ROUTE OF ADMINISTRATION**	**The ivermectin/pyrantel generic chewable tablets are administered orally at monthly intervals during the mosquito (vector for *D. immitis)* season.**
C.	**RECOMMENDED DOSAGES:**	**The ivermectin/pyrantel generic chewable tablets are administered once monthly and provide a minimum of 6 mcg ivermectin per kg of body weight (2.72 mcg/lb) and a minimum of 5 mg pyrantel per kg of body weight (2.27 mg/lb) when given as follows:**

Ivermectin	Pyrantel	Dog Weight
68 mcg	57 mg	Up to 11 kg (25 lb.)
136 mcg	114 mg	12 to 22 kg (26 to 50 lb.)
272 mcg	227 mg	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/pyrantel generic chewable tablet will be identical to the pioneer Heartgard® Plus 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 140-971 approved January 15, 1993 and will include the indications for use which were expanded to include treatment and control of adult hookworms (*Ancylostoma braziliense)* in a supplement to NADA 140-971 approved on October 3, 1996:

INDICATIONS FOR USE:

> **For use in dogs: Ivermectin [to prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for a month (30 days) after infection], and Pyrantel pamoate (for the treatment and control of adult *Toxocara canis, Toxascaris leonina, Ancylostoma caninum, Uncinaria stenocephala* and *Ancyclostoma braziliense).***

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.

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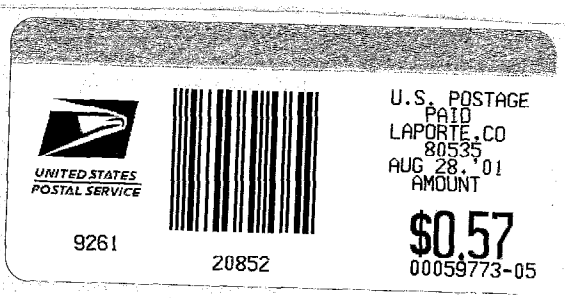

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