



FIRST PRIORITY, INC.

2582 '01 FEB -5 A9:20

CITIZEN PETITION

(ANADA SUITABILITY PETITION)

**First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123
847-289-1600**

01P-0066

CP1



January 31, 2001

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

**CITIZEN PETITION
(ANADA SUITABILITY PETITION)**

First Priority, Inc 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

First Priority, Inc 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.

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:

<u>Ivermectin</u>	<u>Pyrantel</u>	<u>Dog Weight</u>
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 First Priority, Inc.'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 *Ancylostoma braziliense*).

C. Environmental impact

First Priority, Inc 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.



Lawrence Schneider, President
First Priority, Inc
1585 Todd Farm Drive
Elgin, IL 60123-1146

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Deepak Naik Phone 847 289-1600

FIRST PRIORITY INCORP

1585 TODD FARM DR

State IL ZIP 60123

Internal Billing Reference

Dockets Management Brankh Phone

Food & Drug Administration

HFA-305

5630 Fishers Lane, Room 1061

Rockville State MD ZIP 20852



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4a Express Package Service

- FedEx Priority Overnight Next business morning
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 - FedEx First Overnight Earliest next business morning delivery to select locations
 - FedEx 2Day* Second business day
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- * FedEx Envelope/Letter Rate not available. Minimum charge: One-pound rate.

4b Express Freight Service

- FedEx 1Day Freight* Next business day
 - FedEx 2Day Freight Second business day
 - FedEx 3Day Freight Third business day
- * Call for Confirmation.

5 Packaging

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 - Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.
- * Declared value limit \$500

6 Special Handling

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- Include FedEx address in Section 3.

- Does this shipment contain dangerous goods?
One box must be checked.
- No
 - Yes As per attached Shipper's Declaration
 - Yes Shipper's Declaration not required
 - Dry Ice Dry Ice, § UN 1845
 - Cargo Aircraft Only
- Dangerous Goods cannot be shipped in FedEx packaging.

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- Sender Acct. No. in Section 1 will be billed.
 - Recipient
 - Third Party
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- Enter FedEx Acct. No. or Credit Card No. below. Obtain Recip. Acct. No.

Total Packages	Total Weight	Total Charges
		Credit Card Auth.

*Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

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Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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