

8804 '01 SEP 20 A9:22

August 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 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.*

OIP-0425

CP 1

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 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 140-886 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***

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**

RECIPIENT: PEEL HERE

**FedEx**. USA Airbill Tracking Number 824682954662

1 From This portion can be removed for Recipient's records. Date 9/19/01 FedEx Tracking Number 824682954662

Sender's Name MR. DEEPAK NAIK Phone 847 289-1600

Company FIRST PRIORITY INCORP

Address 1585 TODD FARM DR Dept./Floor/Suite/Room

City ELGIN State IL ZIP 60123

2 Your Internal Billing Reference

3 To Recipient's Name Phone

Company ~~FOOD & DRUG~~ ADMINISTRATION

Address HFA-305, DOCKETS MANAGEMENT BRANCH To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

5630 Fishers Lane, Room 1061 Dept./Floor/Suite/Room

City Rockville, State MD ZIP 20852



0158967844

4a Express Package Service Packages up to 150 lbs. Delivery commitment may be later in some areas.  FedEx Priority Overnight Next business morning  FedEx Standard Overnight Next business afternoon  FedEx First Overnight Earliest next business morning delivery to select locations. \* FedEx Envelope/Letter Rate not available. Minimum charge: One-pound rate. Packages over 150 lbs. Delivery commitment may be later in some areas.

4b Express Freight Service Packages over 150 lbs. Delivery commitment may be later in some areas.  FedEx 2Day\* Second business day  FedEx Express Saver\* Third business day  FedEx 1Day Freight\* Next business day  FedEx 2Day Freight Second business day  FedEx 3Day Freight Third business day \* Call for Confirmation.

5 Packaging  FedEx Envelope/Letter\*  Other Pkg. Includes FedEx box, FedEx tape, and customer pkg. \* Declared value limit \$500. 6 Special Handling  SUNDAY Delivery Available for FedEx Priority Overnight to select ZIP codes.  SUNDAY Delivery Available for FedEx Priority Overnight with FedEx First Overnight.  HOLD Weekday at FedEx Location Available for FedEx 2Day Overnight and FedEx 3Day Overnight to select locations.  HOLD Saturday at FedEx Location Available for FedEx 2Day Overnight and FedEx 3Day Overnight to select locations. Does this shipment contain dangerous goods?  No  Yes Shipper's Declaration not required.  Yes Shipper's Declaration required. Dry Ice, 9, UN 1845  Dry Ice Cargo Aircraft Only.  Hazardous Goods cannot be shipped in FedEx packaging.

7 Payment Bill To:  Sender  Recipient  Third Party  Credit Card  Cash/Check  Act. No.  Divan Recip. Enter FedEx Acct. No. or Credit Card No. below.  Dangerous Goods cannot be shipped in FedEx packaging.  No  Yes Shipper's Declaration not required.  Yes Shipper's Declaration required. Dry Ice, 9, UN 1845  Dry Ice Cargo Aircraft Only.  Hazardous Goods cannot be shipped in FedEx packaging.

8 Release Signature  Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.  Total Packages  Total Weight  Total Charges  Credit Card Auth.

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. Visit our Web site at www.fedex.com Questions? Call 1-800-Go-FedEx (800-463-3339)  402

Form ID No. 0215 Recipient's Copy