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September 25, 2002

## SUITABILITY PETITION

Dockets Management Branch  
HFA-305, Room 1061  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

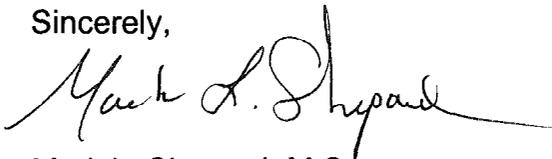
RE: Suitability Petition

Dear Sir/Madam:

Enclosed are four copies of a suitability petition we are filing on behalf of Highland VetPharma, LLC, St. Louis, MO. The petition requests the Commissioner to permit Highland to file an abbreviated new animal drug application (ANADA) for ivermectin/pyrantel having a different dosage form (molded, chewable tablet) than that of the listed approved new animal drug Heartgard<sup>®</sup> Plus (Merial Ltd., NADA 140-971), an extruded chewable tablet.

Please do not hesitate to contact us if additional information is required at this time.

Sincerely,



Mark L. Shepard, M.S.  
Vice President

Enclosure

Cc: Highland VetPharma, LLC

MLS:mlm

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02 R-0423

CPI

# **SUITABILITY PETITION**

**Petition Filed By:**  
**Highland VetPharma, LLC**  
**11960 Westline Drive, Suite 180**  
**St. Louis, Missouri 63146**

**Proposed Product:**  
**A Palatable, Chewable Tablet Form**  
**of Ivermectin/Pyrantel for Dogs**

**Date:**  
**September 25, 2002**



**SUITABILITY PETITION**

The undersigned submits this petition under 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, to request that the Commissioner of Food and Drugs permit Highland VetPharma to file an abbreviated new animal drug application having a dosage form which differs from that of the listed approved new animal drug.

Name: James M. Bausch  
Title: President + COO

9/20/02  
(Date)

I. Action Requested

This action requests the Commissioner to permit the filing of an abbreviated new animal drug application (ANADA) for our proposed product which differs from the approved listed product as follows:

Listed Product (Reference Drug)

Heartgard® Plus (ivermectin/pyrantel), NADA 140-971, originally approved by the Center for Veterinary Medicine on January 15, 1993, and sponsored by Merial Ltd., is an extruded chewable tablet for use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*). It is offered in three formulations containing ivermectin/pyrantel at levels of 68 mcg/57 mg, 136 mcg/114 mg, and 272 mcg/227 mg, respectively. Heartgard® Plus is administered at monthly intervals at the recommended minimum dose of 6 mcg ivermectin and 5 mg pyrantel (as pamoate) per kg of body weight.

Proposed Product

The proposed product is a molded (form-filled) chewable tablet, also to be offered in three formulations containing the same levels of ivermectin and

pyrantel as the approved listed product, which will be indicated for use in dogs for the same claims and will utilize the same oral dosage directions as the listed product. The proposed tablets are packaged in blister packs of six tablets each.

II. Statement of Grounds

Change of dosage form is one of the five specified variances from the listed product which can be considered under a suitability petition pursuant to section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act), as amended. The proposed product differs from the listed product in dosage form. The listed product is an extruded chewable tablet, whereas the proposed product is a molded chewable tablet produced by a method whereby the actual tablet blister is used as the mold for the finished dosage form.

The approval of this petition and the ultimate approval of an abbreviated new animal drug application for a molded palatable, chewable tablet form of ivermectin/pyrantel would provide the dog owner with an alternative to currently available generic ivermectin products (which are compressed chewable tablets) which is readily administered, and is also accepted by the dog as a "treat", similar to the listed product.

The legal basis under which this application proceeds is as promulgated in the FFD&C Act which allows the Commissioner to accept a generic drug application for an animal drug product which differs in dosage form from the listed reference drug product. The dosage form for the proposed generic product described in this petition is similar to that of the listed drug in that both products are oral dosage forms containing the same levels of active ingredients. The difference is that this proposed generic product is in a molded, palatable, chewable tablet form whereas the listed drug is an extruded, palatable, chewable tablet.

The petitioner is not aware of any information which would be unfavorable to the granting of the requested action.

### III. Environmental Impact

Highland VetPharma, LLC hereby claims a categorical exclusion from the requirements of preparing an environmental assessment for this action based on 21 CFR 25.30(h). This subparagraph provides for categorical exclusions for actions such as the issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval. To the best of petitioner's knowledge, no extraordinary circumstances exist which may significantly affect the human environment as discussed under 21 CFR 25.21.

IV. Economic Impact

An economic impact statement pertaining to (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand has not been prepared for this petition. Highland VetPharma will provide such an analysis if so requested by the Commissioner.

V. Identification of Single Listed Reference Drug

NADA NO.	NAME OF DRUG	COMPANY	APPROVAL DATE
140-971	Heartgard® Plus	Merial Ltd.	01/15/93

VI. Labeling

Differences between the proposed generic product labeling and the listed reference product labeling:

I. Box Label (Note: The intermediate sized box is used as illustration; identical respective changes are also made for the other two box sizes.)

A. Side and End Panels

1. Brandname is different
2. Bar code is different (end panel)

B. Front Panel

1. "Highland VetPharma" replaces "Merck"
2. The product brand name is changed to "Brandname."
3. The product number is changed.
4. The patent number is different
5. All other information will change to reflect sponsorship by Highland VetPharma.

II. Package Insert

A. Front Panel

1. The bar code and corresponding number is changed.
2. The NADA number is changed to an ANADA number.
3. The brand name is changed to "Brandname" throughout.

B. Back Panel

1. The brand name is changed throughout.
2. The storage statement is changed to: "Store at a controlled room temperature between 59°F – 86°F (15° – 30° C).
3. Under Adverse Reactions, "Heartgard Plus" is changed to "ivermectin/pyrantel" and "Heartgard" is changed to "ivermectin."

4. Under Safety:

- a. The first sentence of the first paragraph is changed to read, "Brandname has been shown to be equivalent to Heartgard Plus, with respect to the bioavailability of ivermectin and pyrantel."
- b. The second sentence is changed to read, "The dose regimens of Brandname and Heartgard Plus are the same with regard to ivermectin (6 mcg/kg) and pyrantel (5 mg/kg)."
- c. The fifth sentence is changed to read, "Ivermectin has demonstrated no signs of toxicity at 10 times the recommended dose (60 mcg/kg) in sensitive Collies."
- d. In the sixth sentence, "Heartgard" is changed to "ivermectin."
- e. In the first and third sentences of the second paragraph, "Heartgard Plus" is changed to "Ivermectin/pyrantel."

5. Under How Supplied, "Heartgard Plus" is changed to "Brandname" and "6 and 12 chewables" is changed to "6 chewables."
6. In the remainder of the rear insert panel, all information (e.g., phone number for assistance, patent numbers, "Manufactured for", etc.) is changed to reflect sponsorship by Highland VetPharma.

The following pages provide copies of the proposed generic product labeling and the reference drug labeling.

VII. 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 this petition.

Signature:

  
Name of Petitioner: Highland Vet Pharma, LLC

Mailing Address: 11960 Westline Industrial Drive, Ste. 180  
St. Louis, MO 63146

Telephone Number: (314) 205-9666

**PROPOSED GENERIC PRODUCT LABELING**

<b>Brandname</b> (ivermectin/pyrantel)	Lot Exp ▼	<b>Box Top</b>
	<input type="text"/>	26 to 50 lb 6 Chewables

HIGHLAND VETPHARMA	Package Front
<b>Brandname</b> (ivermectin/pyrantel)	
<b>Chewables</b> Each chewable contains 136 mcg ivermectin and 114 mg pyrantel as pamoate salt.	
Administer once a month to prevent heartworm disease to treat and control ascarid and hookworm infections in dogs.	
Recommended for dogs 26 to 50 lb body weight.	
Store at controlled room temperature of 59° - 86°F (15° - 30° C). Protect product from light. Keep this and all drugs out of the reach of children.	
Product XXXXX Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. U.S. Patent X,XXX,XXX Manufactured for: Highland VetPharma, St. Louis, MO 63146	
BRANDNAME is a trademark of Highland VetPharma St. Louis, MO., U.S.A.	Contains 6 Chewables

<b>Brandname</b> (ivermectin/pyrantel)	<b>Box Side 1</b>
	26 to 50 lb 6 Chewables

<b>Brandname</b> (ivermectin/pyrantel)	<b>Box Side 2</b>
	26 to 50 lb 6 Chewables

<b>Brandname</b> (ivermectin/pyrantel)	<b>Box End</b>
	 1332155



BARCODE  
1 2468 369485 7

PACKAGE INSERT

ANADA XXX-XXX, APPROVED BY THE FDA

1 2468 369485 7

**BRANDNAME**

(ivermectin/pyrantel)

**Chewables**

**Caution:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

**INDICATIONS:** For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*).

**DOSAGE:** BRANDNAME should be administered orally at monthly intervals at the recommended minimum dose level of 6 mcg of ivermectin per kilogram (2.72 mcg/lb) and 5 mg of pyrantel (as pamoate salt) per kg (2.27 mg/lb) of body weight. The recommended dosing schedule for prevention of canine heartworm disease and for the treatment and control of ascarids and hookworms is as follows:

Dog Weight	Chewables Per Month	Ivermectin Content	Pyrantel Content	Color Coding On Foil Backing And Carton
Up to 26 lb	1	68 mcg	57 mg	Blue
26 to 50 lb	1	136 mcg	114 mg	Green
51 to 100 lb	1	272 mcg	227 mg	Brown

BRANDNAME is recommended for dogs 6 weeks of age and older. For dogs over 100 lb use the appropriate combination of these chewables.

**ADMINISTRATION:** Remove only one chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to its box to protect the product from light. Because most dogs find BRANDNAME palatable, the product can be offered to the dog by hand. Alternatively, it may be added intact to a small amount of dog food. The chewable should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole.

Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes after administration to ensure that part of the dose is not lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended.

BRANDNAME should be given at monthly intervals during the period of the year when mosquitoes (vectors), potentially carrying infective heartworm larvae, are active. The initial dose must be given within a month (30 days) after the dog's first exposure to mosquitoes. The final dose must be given within a month (30 days) after the dog's last exposure to mosquitoes.

When replacing another heartworm preventive product in a heartworm disease preventive program, the first dose of BRANDNAME must be given within a month (30 days) of the last dose of the former medication.

If the interval between doses exceeds a month (30 days), the efficacy of ivermectin can be reduced. Therefore, for optimal performance, the chewable must be given once a month on or about the same day of the month. If treatment is delayed, whether by a few days or many, immediate treatment with BRANDNAME and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with BRANDNAME also provides effective treatment and control of ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*). Clients should be advised of measures to be taken to prevent reinfection with intestinal parasites.

**EFFICACY:** BRANDNAME (ivermectin/pyrantel) Chewables, given orally using the recommended dose and regimen, are effective against the tissue larval stage of *D. immitis* for a month (30 days) after infection and, as a result, prevent the development of the adult stage. BRANDNAME Chewables are also effective against canine ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*).

**ACCEPTABILITY:** In acceptability and bioequivalence trials, BRANDNAME was shown to be an acceptable oral dosage form that was consumed at first offering by the majority of dogs.

**PRECAUTIONS:** All dogs should be tested for existing heartworm infection before starting treatment with BRANDNAME, which is not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with BRANDNAME.

While some microfilariae may be killed by the ivermectin in BRANDNAME at the recommended dose level, BRANDNAME is not effective for microfilariae clearance. A mild hypersensitivity-type reaction, presumably due to dead or dying microfilariae and particularly involving a transient diarrhea, has been observed in clinical trials with ivermectin alone after treatment of some dogs that have circulating microfilariae.

**Keep this and all drugs out of the reach of children.** In case of ingestion by humans, clients should be advised to contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.

Store at controlled room temperature of 59°F - 86°F (15° – 30°C). Protect product from light.

**ADVERSE REACTIONS:** In clinical field trials with ivermectin/pyrantel, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). The following adverse reactions have been reported following the use of ivermectin: Depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions and hypersalivation.

**SAFETY:** BRANDNAME has been shown to be bioequivalent to HEARTGARD® Plus, with respect to the bioavailability of ivermectin and pyrantel. The dose regimens of BRANDNAME and HEARTGARD® Plus are the same with regard to ivermectin (6 mcg/kg) and pyrantel (5 mg/kg). Studies with ivermectin indicate that certain dogs of the Collie breed are more sensitive to the effects of ivermectin administered at elevated dose levels (more than 16 times the target use level) than dogs of other breeds. At elevated doses, sensitive dogs showed adverse reactions, which included mydriasis, depression, ataxia, tremors, drooling, paresis, recumbency, excitability, stupor, coma and death. Ivermectin has demonstrated no signs of toxicity at 10 times the recommended dose (60 mcg/kg) in sensitive Collies. Results of these trials and bioequivalency studies, support the safety of ivermectin products in dogs, including Collies, when used as recommended.

Ivermectin/pyrantel has shown a wide margin of safety at the recommended dose level in dogs, including pregnant or breeding bitches, stud dogs and puppies aged 6 or more weeks. In clinical trials, many commonly used flea collars, dips, shampoos, anthelmintics, antibiotics, vaccines and steroid preparations have been administered with ivermectin/pyrantel in a heartworm disease preventive program.

In one trial, where some pups had parvovirus, there was a marginal reduction in efficacy against intestinal nematodes, possibly due to a change in intestinal transit time.

**HOW SUPPLIED:** BRANDNAME is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient cartons of 6 chewables.

For customer assistance, please contact Highland at 1-888-xxx-xxxx.

Manufactured for:  
Highland VetPharma  
St. Louis, MO 63146

U.S. Pat. X,XXX,XXX  
© 2002 Highland VetPharma  
Made in U.S.A.  
November 2002

**REFERENCE PRODUCT LABELING**

Lot & Exp  
**Heartgard™ Plus**  
(ivermectin/pyrantel)

**EBD057**  
**AUG00**

**26 to 50 lb**  
**6 Chewables**



# Heartgard™ Plus

(ivermectin/pyrantel)

## Chewables

Each chewable contains 136 mcg ivermectin and 114 mg pyrantel as pamoate salt.

Administer once a month to prevent heartworm disease and to treat and control ascarid and hookworm infections in dogs.

**Recommended for dogs 26 to 50 lb body weight.**

Store at controlled room temperature of 59°–86°F (15°–30°C).

Protect product from light.

Keep this and all drugs out of the reach of children.

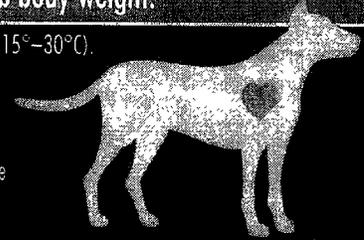
Product **37812**

**Caution:** Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

U.S. Pat. 4,199,569

Merck Ag/Ver Division, Merck & Co., Inc., Rahway, N.J., 07065-0912

**HEARTGARD** is a trademark of Merck & Co., Inc.  
Whitehouse Station, N.J., U.S.A.



Contains 6 Chewables

Heartgard™ Plus  
(ivermectin/pyrantel)

26 to 50 lb  
6 Chewables

26 to 50 lb  
6 Chewables

Heartgard™ Plus  
(ivermectin/pyrantel)

**Heartgard™ Plus**  
(ivermectin/pyrantel)



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REX:Am

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08823114

NADA 140-971, Approved by the FDA

8823114

# Heartgard<sup>®</sup> <sup>TM</sup> (ivermectin/pyrantel) Plus

## Chewables

**Caution:** Federal (U S A ) law restricts this drug to use by or on the order of a licensed veterinarian.

**INDICATIONS:** For use in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*)

**DOSAGE:** HEARTGARD<sup>®</sup> Plus should be administered orally at monthly intervals at the recommended minimum dose level of 6 mcg of ivermectin per kilogram (2.72 mcg/lb) and 5 mg of pyrantel (as pamoate salt) per kg (2.27 mg/lb) of body weight. The recommended dosing schedule for prevention of canine heartworm disease and for the treatment and control of ascarids and hookworms is as follows

Dog Weight	Chewables Per Month	Ivermectin Content	Pyrantel Content	Color Coding on Foil Backing and Carton
Up to 25 lb	1	68 mcg	57 mg	Blue
26 to 50 lb	1	136 mcg	114 mg	Green
51 to 100 lb	1	272 mcg	227 mg	Brown

HEARTGARD Plus is recommended for dogs 6 weeks of age and older  
For dogs over 100 lb use the appropriate combination of these chewables

**ADMINISTRATION:** Remove only one chewable at a time from the foil-backed blister card. Return the card with the remaining chewables to its box to protect the product from light. Because most dogs find HEARTGARD Plus palatable, the product can be offered to the dog by hand. Alternatively, it may be added intact to a small amount of dog food. The chewable should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole.

Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes after administration to ensure that part of the dose is not lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended.

HEARTGARD Plus should be given at monthly intervals during the period of the year when mosquitoes (vectors), potentially carrying infective heartworm larvae, are active. The initial dose must be given within a month (30 days) after the dog's first exposure to mosquitoes. The final dose must be given within a month (30 days) after the dog's last exposure to mosquitoes.

When replacing another heartworm preventive product in a heartworm disease preventive program, the first dose of HEARTGARD Plus must be given within a month (30 days) of the last dose of the former medication.

If the interval between doses exceeds a month (30 days), the efficacy of ivermectin can be reduced. Therefore, for optimal performance, the chewable must be given once a month on or about the same day of the month. If treatment is delayed, whether by a few days or many, immediate treatment with HEARTGARD Plus and resumption of the recommended dosing regimen minimizes the opportunity for the development of adult heartworms.

Monthly treatment with HEARTGARD Plus also provides effective treatment and control of ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*). Clients should be advised of measures to be taken to prevent reinfection with intestinal parasites.

HEARTGARD is a registered trademark and Dog & Hand logo is a trademark of Merial.

**EFFICACY:** HEARTGARD® Plus (ivermectin/pyrantel) Chewables, given orally using the recommended dose and regimen, are effective against the tissue larval stage of *D. immitis* for a month (30 days) after infection and, as a result, prevent the development of the adult stage. HEARTGARD Plus Chewables are also effective against canine ascarids (*T. canis*, *T. leonina*) and hookworms (*A. caninum*, *U. stenocephala*, *A. braziliense*)

**ACCEPTABILITY:** In acceptability and field trials, HEARTGARD Plus was shown to be an acceptable oral dosage form that was consumed at first offering by the majority of dogs

**PRECAUTIONS:** All dogs should be tested for existing heartworm infection before starting treatment with HEARTGARD Plus which is not effective against adult *D. immitis*. Infected dogs must be treated to remove adult heartworms and microfilariae before initiating a program with HEARTGARD Plus

While some microfilariae may be killed by the ivermectin in HEARTGARD Plus at the recommended dose level, HEARTGARD Plus is not effective for microfilariae clearance. A mild hypersensitivity-type reaction, presumably due to dead or dying microfilariae and particularly involving a transient diarrhea, has been observed in clinical trials with ivermectin alone after treatment of some dogs that have circulating microfilariae.

**Keep this and all drugs out of the reach of children.** In case of ingestion by humans, clients should be advised to contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans

Store between 68°F - 77°F (20° - 25°C) Excursions between 59°F - 86°F (15 - 30°C) are permitted. Protect product from light

**ADVERSE REACTIONS:** In clinical field trials with HEARTGARD Plus, vomiting or diarrhea within 24 hours of dosing was rarely observed (1.1% of administered doses). The following adverse reactions have been reported following the use of HEARTGARD: Depression/lethargy, vomiting, anorexia, diarrhea, mydriasis, ataxia, staggering, convulsions and hypersalivation.

**SAFETY:** HEARTGARD Plus has been shown to be bioequivalent to HEARTGARD, with respect to the bioavailability of ivermectin. The dose regimens of HEARTGARD Plus and HEARTGARD are the same with regard to ivermectin (6 mcg/kg). Studies with ivermectin indicate that certain dogs of the Collie breed are more sensitive to the effects of ivermectin administered at elevated dose levels (more than 16 times the target use level) than dogs of other breeds. At elevated doses, sensitive dogs showed adverse reactions which included mydriasis, depression, ataxia, tremors, drooling, paresis, recumbency, excitability, stupor, coma and death. HEARTGARD demonstrated no signs of toxicity at 10 times the recommended dose (60 mcg/kg) in sensitive Collies. Results of these trials and bioequivalency studies, support the safety of HEARTGARD products in dogs, including Collies, when used as recommended.

HEARTGARD Plus has shown a wide margin of safety at the recommended dose level in dogs, including pregnant or breeding bitches, stud dogs and puppies aged 6 or more weeks. In clinical trials, many commonly used flea collars, dips, shampoos, anthelmintics, antibiotics, vaccines and steroid preparations have been administered with HEARTGARD Plus in a heartworm disease preventive program.

In one trial, where some pups had parvovirus, there was a marginal reduction in efficacy against intestinal nematodes, possibly due to a change in intestinal transit time.

**HOW SUPPLIED:** HEARTGARD Plus is available in three dosage strengths (See DOSAGE section) for dogs of different weights. Each strength comes in convenient cartons of 6 and 12 chewables.

For customer assistance, please contact Merial at 1-888-637-4251

Marketed by  
Merial Limited  
Iselin, NJ 08830-3077

(Merial Limited Registered in England and Wales [Reg. No. 3332751] with registered offices at 27 Knightsbridge, London, SW1X 7QT, England and domesticated in Delaware, USA as Merial LLC)

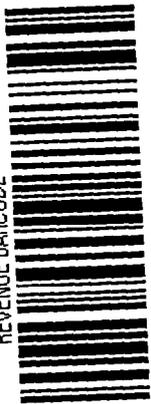
U.S. Pat. 4,199,569  
© 2000 Merial. All Rights Reserved.  
Made in U.S.A.  
November 2000



FedEx | Ship Manager | Label7900 8159 1076

From: MARK SHEPARD (972)355-9700  
SHOTWELL & CARR, INC  
3535 FIREWHEEL DRIVE  
SUITE A  
FLOWER MOUND, TX, 75028

REVENUE BARCODE



To: Dockets Management Branch (301)827-6860  
Food & Drug Administration  
HFA-305, Room 1061  
5630 Fishers Lane  
Rockville, MD, 20852

SHIP DATE: 25SEP02  
WEIGHT: 2 LBS

Ref: ADCT 239



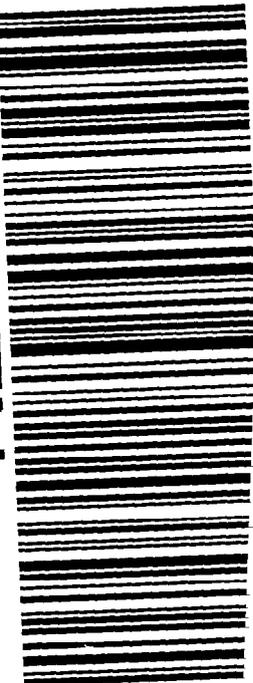
DELIVERY ADDRESS BARCODE(FEDEN-EDR)

TRK # 7900 8159 1076 6981

FedEx PRIORITY OVERNIGHT  
IAD

NZ GAIA

20852-MD-US



THU  
A2

Deliver by:  
26SEP02