Date of Approval: May 23, 2008

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-189

PROHEART 6 Sustained Release Injectable for Dogs

(Moxidectin)
Dogs over 6 months of age

This supplement provides for the revision of the animal safety information in the warning, precaution, adverse reactions, and post-approval sections of the product labeling.

Sponsored by:

Fort Dodge Animal Health
Division of Wyeth

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I. GENERAL INFORMATION:

A. File Number:	NADA 141-189
B. Sponsor:	Fort Dodge Animal Health Division of Wyeth 800 Fifth St., NW. Fort Dodge, IA 50501 Drug Labeler Code: 000856
C. Proprietary Name(s):	PROHEART 6 Sustained Release Injectable for Dogs
D. Established Name(s):	Moxidectin
E. Pharmacological Category:	Antiparasitic
F. Dosage Form(s):	Sterile Suspension
G. Amount of Active Ingredient(s):	Each mL of constituted suspension contains 3.4 mg moxidectin.
H. How Supplied:	ProHeart 6 consists of two separate vials. Vial 1 contains 10% moxidectin sterile microspheres and Vial 2 contains sterile vehicle for constitution. ProHeart 6 is available in two sizes: 20 mL size (598 mg/vial moxidectin plus 17 mL/vial sterile vehicle) 50 mL size (1,549 mg/vial moxidectin plus 44 mL/vial sterile vehicle)
I. How Dispensed:	Rx
J. Dosage(s):	The recommended subcutaneous dose is 0.05 mL of the constituted suspension/kg body weight (0.227 mL/lb). This amount of suspension will provide 0.17 mg moxidectin/kg body weight (0.0773 mg/lb).
K. Route(s) of Administration:	Subcutaneous injection
L. Species/Class(es):	Dogs over 6 months of age
M. Indication(s):	ProHeart 6 is indicated for use in dogs six

months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis*. ProHeart 6 is indicated for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

N. Effect(s) of Supplement: This supplement provides for the revision of the animal safety information in the warning, precaution, adverse reactions, and post-approval sections of the product labeling.

II. EFFECTIVENESS:

A. Dosage Characterization:

This supplemental approval does not change the previously approved dosage. The Freedom of Information (FOI) Summary for the original approval of NADA 141-189 dated June 6, 2001, and a supplemental approval dated June 13, 2002, contain dosage characterization information for dogs over 6 months of age.

B. Substantial Evidence:

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-289 dated June 6, 2001, and a supplemental approval dated June 13, 2002, contain a summary of studies that demonstrate effectiveness of the drug for dogs over 6 months of age.

III. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-189 dated June 6, 2001, and a supplemental approval dated June 13, 2002, contain a summary of target animal safety studies for dogs over 6 months of age.

IV. HUMAN FOOD SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

V. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to PROHEART 6 Sustained Release Injectable for Dogs:

Not for human use. Keep this and all drugs out of the reach of children.

May be slightly irritating to the eyes. May cause slight irritation to the upper respiratory tract if inhaled. May be harmful if swallowed. If contact with the eyes occurs, rinse thoroughly with water for 15 minutes and seek medical attention immediately. If accidental ingestion occurs, contact a Poison Control Center or a physician immediately. The material safety data sheet (MSDS) contains more detailed occupational safety information.

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 514. The data demonstrate that PROHEART 6 Sustained Release Injectable for Dogs, when used according to the label, is safe and effective for use in dogs six months of age and older for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

A. Marketing Status:

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional expertise is required to properly administer the injection, provide adequate instructions for post treatment care, and to monitor the safe use of the product, including treatment of any adverse reactions.

B. Exclusivity:

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

C. Supplemental Applications:

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR 514.106(b)(2)).

D. Patent Information:

The sponsor did not submit any patent information with this application.

VII. ATTACHMENTS:

Labeling:

a) Package Insert:
   i) 20 mL Presentation

ii) 20 mL and 50 mL Presentation

b) Client Information Sheets:
   i) Back of Package Insert 20 mL Presentation (Code 3670G)
   ii) Back of Package Insert 20 mL and 50 mL Presentation (Code 3671G)

c) Vial Labeling:
   i) 598 mg Moxidectin Sterile Microspheres
   ii) 17 mL Sterile Vehicle
   iii) 1549 mg Moxidectin Sterile Microspheres
   iv) 44 mL Sterile Vehicle

d) Carton Labeling:
   i) Single Pack – 20 mL Presentation
   ii) 5- Pack – 20 mL Presentation
   iii) 10- Pack – 20 mL Presentation
   iv) Single Pack – 50 mL Presentation