NOBLE PHARMA LLC
a Vets Plus Company

April 1, 2019

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

Re: ANADA Suitability Petition for an Alternate Dosage Form

Dear Sir or Madam:

Enclosed please find a Suitability Petition submitted by Noble Pharma, LLC in accordance with Section 512(n)(3) of the Federal Food, Drug and Cosmetic Act (FFDCA) to request the Commissioner of Food and Drug Administration to determine suitability of an ANADA filing for a generic flavored soft chewable of a combination ivermectin and pyarantel (as pamoate salt) which differs in the dosage form from the reference product, Heartgard® Plus, approved under NADA 140 – 971 for Merck & Co., Inc., and marketed by Boehringher Ingelheim Animal Health USA Inc. The proposed generic product will be an extruded and flavored scored soft chewable, whereas the pioneer product is an extruded beef flavored chewable tablet.

Should you have questions, please contact me at (715) 231-1234 X302 or by email at dnelson@noblepharmallc.com.

Sincerely,

David Nelson
President, Noble Pharma, LLC

Suitability Petition

Identification of the Petitioner:

Noble Pharma, LLC
4602 Domain Drive
Menomonie, WI 54751

Citation:

Noble Pharma, LLC submits this Suitability Petition under Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Action Requested:

The petitioner requests permission from the Commissioner of the Food and Drug Administration to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form of an approved pioneer product. The pioneer product (reference product), Heartgard® Plus, approved under NADA 140 – 971, is registered under Merck & Co., Inc., and marketed by Boehringer Ingelheim Animal Health USA Inc. The proposed generic product, trade name to be determined (TBD), is an extruded and scored soft chewable. The method of administration (oral) will be the same as that for the pioneer product. The amount of active ingredient will be the same for both the pioneer and generic products. The copies of the pioneer and proposed product labels are provided in Appendices 1 and 2, respectively.

Statement of Grounds:

The active ingredients in the pioneer product, Heartgard® Plus, are ivermectin and pyrantel pamoate formulated as a beef-based chewable tablet. The product is administered orally for the prevention of heartworm disease and to treat and control preexisting hookworm and roundworm infections in dogs (see Table 1 for details). The proposed generic product, administered orally, will have the same active ingredient, indications and dosage, have the same therapeutic effect and contain the same cautions and warnings as the pioneer product. The pioneer product is an extruded beef-flavored tablet compared to an extruded and flavored soft chewable with a score on top for the proposed generic product.

Table 1.

Parameter	Pioneer Product – Heartgard® Plus For Dogs	Proposed Generic Product – Trade Name (TBD)
Regulatory ID	NADA – 140 - 971	TBD
Species	Dog	Dog
Active Ingredient	Ivermectin and Pyrantel pamoate	Ivermectin and Pyrantel pamoate
Pharmacological category	Parasiticide	Parasiticide
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 (**ivermectin**) and for the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense (***pyrantel pamoate**).	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 form	Beef-flavored chewable tablet	Flavored and scored soft chewable
Use directions*	Dogs up to 25 lbs. 1 chewable tablet 68 mcg (ivermectin), 57 mg (pyrantel) Dogs 26 to 50 lbs., 1 chewable tablet 136 mcg (ivermectin, 114 mg (pyrantel) Dogs 51 to 100 lbs, 1 chewable tablet 272 mcg (ivermectin), 227 mg (pyrantel)	Dogs up to 25 lbs. 1 chewable tablet 68 mcg (ivermectin), 57 mg (pyrantel) Dogs 26 to 50 lbs., 1 chewable tablet 136 mcg (ivermectin, 114 mg (pyrantel) Dogs 51 to 100 lbs, 1 chewable tablet 272 mcg (ivermectin), 227 mg (pyrantel)
Route of administration	Oral	Oral

*Heartgard® Plus is recommended for dogs 6 weeks and older. For dogs over 100 lbs use appropriate combination of these chewable tablets.

The proposed generic drug will provide an alternative dosage form to veterinarians and dog owners. Soft chewable dosage forms are more palatable and dogs of all ages will find it easier to chew than a tablet, thus making it easier to achieve compliance. Unlike

the pioneer drug, the proposed soft chewable can be administered to a dog without crumbling or mixed with feed. Having a score on the chewable provides an advantage to owners of dogs with multiple weight range. All of the excipients in the new dosage form are already in use for products approved for dogs and will not adversely impact the safety and effectiveness of ivermectin and pyrantel in the new formulation.

The labeling for the proposed generic product will parallel the pioneer product and include the following categories: Description, Uses, Dosage and Administration, Retreatment, Side Effects, Warning, How Supplied, Storage Conditions, and the manufacturer's information.

The labels of the two products differ in the type of formulation: an un-scored beef flavored tablet for the pioneer product compared to a scored and flavored soft chewable for the proposed generic product. The labeling will also differ as it relates to the different companies manufacturing the two products, the trade name, the texture and hardness of the two products. The storage condition of the proposed product may differ from that of the pioneer depending on the results of the product stability testing. The parts of the proposed generic product label (draft) that will be different are highlighted and attached to this petition (See Appendix 2).

Environmental Impact:

In accordance with 21 CFR 25.15, Noble Pharma, LLC claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR 25.30(h). We confirm that to our knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

Economic Impact:

Noble Pharma, LLC will provide an economic impact analysis of this action if requested by the commissioner after review of this Suitability Petition.

Confidential and/or Proprietary Information:

In accordance with applicable provisions of the Freedom of Information Act (FOIA) and 21 CFR 20.61, Petitioner declares that no information contained within this Suitability Petition constitutes privileged or confidential trade secrets and/or commercial or financial information exempt from disclosure under exemption 4 of FOIA.

Certification:

The Petitioner, Noble Pharma, LLC, certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petition relies, including representative data and information known to be unfavorable to the petition.

4/1/19

David Nelson
President, Noble Pharma, LLC
4602 Domain Dr.
Menomonie, WI 54751

Date

Enclosures:

Appendix 1 - Pioneer Product Label
Appendix 2 – Proposed Generic Product Label (Draft) – Differences from the Pioneer Label are highlighted