NOBLE PHARMA LLC
a Vets Plus Company

June 24, 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 chew, a combination of pyrantel pamoate and praziquantel, which differs in the dosage form from the reference product, Virbantel® approved under NADA 141 – 261 for Virbac AH, Inc. USA. The proposed generic product will be an extruded and flavored soft chew, whereas the pioneer product appears to be a compressed pork liver flavored chewable.

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), Virbantel®, approved under NADA 141 – 265, is registered under Virbac AH, Inc. USA. The proposed generic product, trade name to be determined (TBD), is an extruded and flavored soft chew. 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, Virbantel®, are pyrantel pamoate and praziquantel. The product is commercially available as a pork liver flavored chewable form in two different strengths, 30mg/30mg (pyrantel pamoate/praziquantel) and 114mg/114mg (pyrantel pamoate/praziquantel). The dose for each drug is 2.27 mg per pound of body weight (5 mg/Kg of body weight). The product is administered orally for the treatment and prevention of roundworms, hookworms and tapeworms in dogs and puppies (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 appears to be a compressed pork liver flavored chewable compared to an extruded and chicken liver flavored soft chew for the proposed generic product.

Table 1.

Parameter	Pioneer Product – Virbantel® For Dogs	Proposed Generic Product – Trade Name (TBD)
Regulatory ID	NADA – 141 - 261	TBD
Species	Dog	Dog
Active Ingredient	Pyrantel pamoate and Praziquantel	Pyrantel pamoate and Praziquantel
Pharmacological category	Parasiticide	Parasiticide
Indications	For use in dogs for the treatment and control of **roundworms** (*Toxocara canis, Toxascaris leonina*), **hookworms** (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*), **and tapeworms** (*Dipylidium caninum, Taenia pisiformis*).	For use in dogs for the treatment and control of **roundworms** (*Toxocara canis, Toxascaris leonina*), **hookworms** (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*), **and tapeworms** (*Dipylidium caninum, Taenia pisiformis*).
Dosage form	Pork liver flavored chewable	Chicken liver flavored soft chew
Use directions	Dogs 6.0 to 12 lbs. 1 Chewable (30 mg) Dogs 12.1 to 25 lbs. 2 Chewables (30 mg) Dogs 25.1 to 50 lbs. 1 Chewables (114 mg) Dogs 50.1 to 100 lbs. 2 Chewables (114 mg) Dogs 100.1 to 150 lbs. 3 Chewables (114 mg) Dogs 150.1 to 200 lbs. 4 Chewables (114 mg)	Dogs 6.0 to 12 lbs. 1 Soft chews (30 mg) Dogs 12.1 to 25 lbs. 2 Soft chews (30 mg) Dogs 25.1 to 50 lbs. 1 Soft chews (114 mg) Dogs 50.1 to 100 lbs. 2 Soft chews (114 mg) Dogs 100.1 to 150 lbs. 3 Soft chews (114 mg) Dogs 150.1 to 200 lbs. 4 Soft chews (114 mg)
Route of administration	Oral	Oral

The proposed generic drug will provide an alternative dosage form to veterinarians and dog owners. Soft chew dosage forms are more palatable, and dogs of all ages will find it easier to chew than a harder chewable form, thus making it easier to achieve compliance. When administered, the dog may either chew the drug before swallowing or swallow it intact. Mixing the drug with food and force-feeding to achieve compliance may not be necessary. 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 pyrantel pamoate and praziquantel 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: a pork liver flavored chewable for the pioneer product compared to a chicken liver flavored soft chew form 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). Product Labels for both strengths, 30 mg and 114 mg that cover weight range of dogs and puppies from 6 lbs. to 200 lbs. are presented.

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.

David Nelson

6-24-2019

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

Date

Enclosures:

Appendix 1 - Pioneer Product Label. Labels for small (6-25 lbs.) and medium to large (25.1-200 lbs.) dogs are presented.
Appendix 2 – Proposed Generic Product Label (Draft) – Differences from the Pioneer Label are highlighted