NOBLE PHARMA LLC
a Vets Plus Company

Date: July 23, 2019

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

Amended Petition for reconsideration

Docket No. (FDA-2019-P-1566)

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drug Administration in Docket No. (FDA-2019-P-1566)

A. Decision involved:

Noble Pharma submitted a suitability petition (FDA-2019-P-1566) dated April 1, 2019 and requested permission to submit an abbreviated new animal drug application (ANADA) for a generic ivermectin and pyrantel (as the pamoate salt) chewable with an additional score". The request was denied by the Commissioner of Food and Drug Administration on June 25, 2019.

The Agency stated that "The proposed generic new animal drug is a scored, poultry-flavored chewable. The RLNAD is a beef-flavored chewable. A change in flavoring and degree of hardness within a chewable dosage form are not changes which warrant pursuit of a suitability petition".

B. Action requested:

Noble Pharma respectfully requests that the Commissioner reconsider its June 25, 2019 decision denying the request to submit an abbreviated new animal drug application (ANADA) for generic ivermectin and pyrantel (as pamoate salt) chewable.

C. Statement of grounds:

Noble Pharma would like to submit the following information to demonstrate the difference between the pioneer, Heartgard® Plus tablet, and our proposed chewable tablet, in size, texture, and presumably the composition and type of excipients, for your re-consideration. The information presented herein is merely provided to elaborate the differences between the two dosage forms and I do not consider them as additional data that was not included in the original petition according to 21 CFR 10.33 (e).

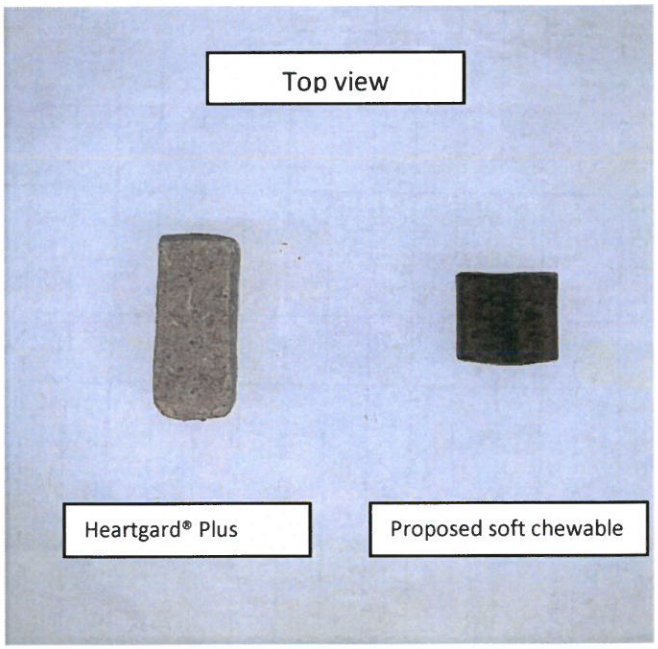
1. Composition of excipients of the chewable:

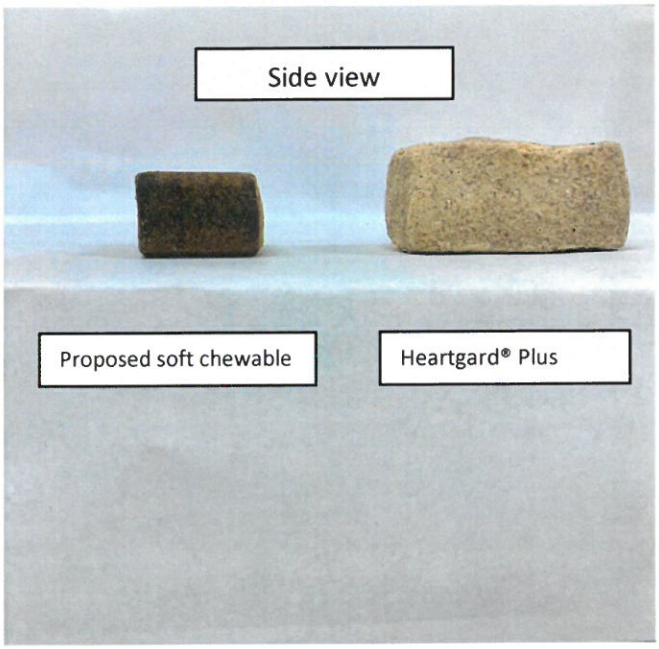
In the absence of publicly available data on the excipients in the pioneer product, we are unable to make a direct comparison between the excipients used in our formulation with those of the pioneer. However, a person with the expertise in the art of formulation of drugs should be able

to make a visual comparison and deduce that they are different in texture and presumably the type of excipients used. Our formulation appears to be softer and more pliable than the pioneer drug. Noble Pharma provided some hardness data in comparison with the pioneer on May 10, 2019 in response to a request from the FDA. In comparison with the pioneer, we consider our proposed chicken liver-flavored formulation is more appealing to dogs, and dosing restrictions as in the case of the pioneer drug do not apply to the proposed formulation. We will be more than happy to provide the list of excipients used in our proprietary formulation for your review separately upon request.

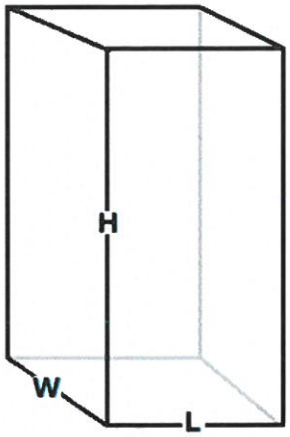
2. Comparison of the size:

   The images below clearly illustrate the size difference between the two products, the pioneer Vs the proposed chewable tablet.

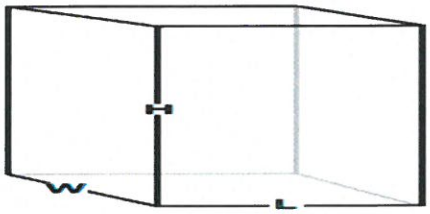




The dimensions of the two tablets are given below:



Heartgard® Plus



Proposed Soft Chewable

Parameters	**Heartgard® Plus (mm)**	**Proposed Soft Chewable (mm)**
Height	36.5	10.5
Length	14.5	18.3
Width	13.3	18.1
Volume (mm^3)	7039 mm^3	3478 mm^3

The above data demonstrate the differences in size of the two dosage forms. Dog owners and the veterinarians prefer smaller and softer tablets to eliminate the possibility of choking.

3. Scoring of the tablets:

   Noble Pharma proposes to remove scoring of the chewable as stated in the suitability petition.

4. Precedence:
   Noble Pharma believes that the Provetica's suitability petition (FDA-2018-P-1185) claimed a flavored soft tab as the change in dosage form from the pioneer, Heartgard® Plus, and the change is similar to what we proposed in our petition. The pioneer is a beef-flavored chewable tablet manufactured by extrusion. Provetica's generic copy is a meat-flavored soft tab manufactured by extrusion. The latter is formulated in a poultry digest and beef-flavored matrix. The petition (FDA-2018-P-1185) was approved by the Agency on June 13, 2018.

D. Conclusion:

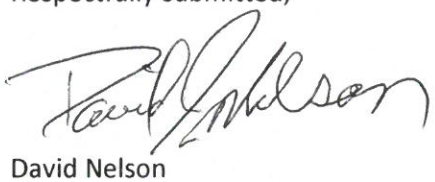
The pioneer is a beef-flavored extruded chewable tablet and the proposed generic form by Noble Pharma is a chicken liver-flavored extruded soft chewable tablet. The chicken liver-flavored soft chewable provides a palatable and an appealing formulation to the dogs in general and more specifically an alternative to dogs who suffer from beef protein allergies. Dosing restrictions such as mixing the dose with food, breaking up into smaller pieces, or force feeding should not be necessary when administering the proposed generic version to dogs.

In light of the above differences between the pioneer product and the proposed chewable tablet, Noble Pharma respectfully requests that the Commissioner grants the action requested in this petition and reconsider your June 25, 2019 decision on our suitability petition (FDA-2019-P-1566). An amended version of the petition with scoring removed is attached.

E. 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.

Respectfully submitted,



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