



SCHAFER VETERINARY CONSULTANTS, LLC

February 21, 2019

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

RE: Suitability Petition for Revised Dosage Form of Praziquantel
and Pyrantel Pamoate Tablets

Division of Dockets Management:

As the US Agent for Felix Pharmaceuticals Pvt. Ltd., 25-28, North Wall Quay, Dublin 1,
Republic of Ireland, I am submitting a suitability petition for Agency review and action.

The Sponsor is requesting permission to file an abbreviated new animal drug
application (ANADA) for a generic chewable tablet for Praziquantel and Pyrantel
Pamoate that differs from the pioneer product, DRONTAL® Tablets, sponsored by Bayer
Healthcare LLC, under NADA 141-008. The RLNAD is approved as a compressed
tablet and the proposed generic product is a compressed chewable tablet.

There are three appendices to this letter:

1. A suitability petition signed by the Sponsor describing in detail the proposed
change.
2. A copy of the Bayer Healthcare LLC package insert for this product.
3. An annotated copy of the package insert showing Felix's proposed changes.

Please feel free to contact me by telephone or email if you should have any questions.

Sincerely,

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