



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 27, 2019

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

Sent via email to: dnelson@noblepharmallc.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA 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 was received by this office on 06/26/2019.

It was assigned docket number FDA-2019-P-3109. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)