



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 25, 2019

James H. Schafer, D.V.M.
Schafer Veterinary Consultants, LLC
US Agent for Felix Pharmaceuticals Private Limited
800 Helena Court
Fort Collins, CO 80524

Sent via email to: jschafer@svcreg.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner grant permission to file an application for an abbreviated new animal drug application (ANADA) for a generic compressed chewable tablet for Praziquantel that differs from the pioneer product, DRONCIT® Tablets, sponsored by Bayer Healthcare LLC, under NADA 111-798 was received by this office on 02/25/2019.

It was assigned docket number FDA-2019-P-0916. 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 the Executive Secretariat (OES)