



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 28, 2019

Stephen Organ
Summit Pharmaceuticals Inc.
950 Echo Lane
Houston, TX 77024

Sent via email to: sorgan@svprx.ca

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner allow petitioner to file an Abbreviated New Animal Drug Application based on NADA 141-324 "PROIN Chewable Tablets" for dogs (the "RLNAD") was received by this office on 12/21/2018.

It was assigned docket number FDA-2019-P-0412. 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)