SUMMIT

Summit Pharmaceuticals Inc.
950 Echo Lane
Houston, TX
77024

December 21, 2018

Food and Drug Administration
Division of Dockets Management
ATTN: Center For Veterinary Medicine
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

*Transmitted electronically via www.regulations.gov (under docket no. FDA-2013-S-0610)*

**RE: Suitability Petition Against NADA 141-324**

Dear Sir or Madam:

Enclosed is a Suitability Petition ("the Petition") submitted on behalf of Summit Pharmaceuticals Inc. in accordance with § 512(n)(3) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 10.20 and 10.30. The Petition requests permission to file an Abbreviated New Animal Drug Application based on NADA 141-324 – "PROIN Chewable Tablets" for dogs (the "RLNAD"). The generic product will differ from the RLNAD in two ways: (i) the RLNAD consists of scored, chewable tablets whereas the proposed generic will consist of unscored, film-coated tablets and (ii) the proposed generic will include two additional dosage strengths to account for lack of tablet scoring.

If you have any questions regarding the Petition or need to contact me directly for any reason, please don't hesitate to call or email me (905-713-2040 x211; sorgan@svprx.ca). I appreciate you taking the time to consider the content of the Petition.

Sincerely,

Stephen D. Organ
President
Summit Pharmaceuticals Inc.

# SUITABILITY PETITION AGAINST NADA 141-324

**Petitioner:** Summit Pharmaceuticals Inc.
950 Echo Lane
Houston, TX
77024

The undersigned submits this Petition pursuant to § 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 C.F.R. §§ 10.20 and 10.30, to request the Commissioner of Food and Drugs to grant Summit Pharmaceuticals Inc. ("Summit") permission to file an Abbreviated New Animal Drug Application based on PROIN Chewable Tablets – approved under NADA 141-324 (the "RLNAD") – that seeks approval of a generic that differs from the RLNAD in (i) dosage form and (ii) dosage strength.

## A. Action Requested

The label of the RLNAD is attached hereto as Appendix 1. The Freedom of Information Summary of the RLNAD is attached hereto as Appendix 2. Per the label, "PROIN is scored and contains 25, 50, or 75 mg phenylpropanolamine hydrochloride per tablet." App. 1, under "How Supplied." The FOI Summary confirms that the RLNAD is supplied as scored chewable tablets in three dosage strengths: 25, 50, and 75 mg of phenylpropanolamine hydrochloride. App. 2, p. 1. The label and FOI Summary state the following indication for the RLNAD: "PROIN is indicated for the control of urinary incontinence due to urethral sphincter hypotonus in dogs." App. 1, under "Indication"; App. 2, p.1. Lastly, both the label and FOI Summary state that the RLNAD is formulated for oral administration, while noting the following regarding dosage: "[t]he total recommended dosage for oral administration is 2 mg/kg (0.91 mg/lb) of body weight twice daily [...] dosage should be calculated in half-tablet increments." App. 1, under "Dosage and Administration"; App. 2, p.1.

Summit wishes to develop and have approved a generic of the RLNAD that deviates from the RLNAD in two ways. First, Summit proposes to alter the **dosage form** by developing unscored, film-coated tablets comprising phenylpropanolamine hydrochloride rather than scored, chewable tablets. Second, to account for the fact that Summit's tablets will be unscored, Summit proposes to develop two additional **dosage strengths – 12.5 mg** and **37.5 mg** phenylpropanolamine hydrochloride tablets – to ensure the range of Summit's tablets is the same as the range covered by the half-tablet increments of the RLNAD. The table below summarizes the changes in dosage form and strength Summit wishes to develop.

| | RLNAD | Summit Generic |
|---|---|---|
| **Form** | Scored chewable tablets | Unscored film-coated tablets |
| **Strength** | 25, 50, and 75 mg | 12.5 and 37.5 mg<br>(*in addition to* 25, 50, and 75 mg) |

## B. Statement of Grounds

*Factual Grounds*

***Ingredients.*** Summit does not intend to alter the active ingredient of the RLNAD nor include any additional active ingredient(s) in its proposed generic. Therefore, the generic product proposed by Summit will contain the same active ingredient (phenylpropanolamine) as the RLNAD. Excipients (non-active ingredients) of Summit's proposed generic will consist of those used in products currently approved by the Center for Veterinary Medicine (CVM) for companion animal use.

***Labeling.*** Save for labeling distinctions dictated by the difference in corporate entities responsible for manufacture, product trade names, and changes in dosage form and strength of Summit's proposed generic, Summit intends to label its product in the same manner as the RLNAD, including all listed warnings, precautions, and other relevant user information. Appendix 3 presents a version of the RLNAD label with highlighting of parts of the label that will be changed. Proposed labeling with respect to the indication, dosage and administration, and supply of Summit's generic product are provided in the table below.

| | **Summit Generic: Proposed Labeling** |
|---|---|
| **Indication** | Indicated for the control of urinary incontinence due to urethral sphincter hypotonus in dogs. |
| **Dosage and Administration** | The total recommended dosage for oral administration is 2 mg/kg (0.91 mg/lb) of body weight twice daily. |
| **How Supplied** | [Summit's product] contains 12.5, 25, 37.5, 50, or 75 mg of phenylpropanolamine hydrochloride per tablet. [Summit's product] is packaged in bottles containing 60 or 180 tablets. |

***Route of Administration.*** As noted in the proposed labeling above, Summit's generic will be administered orally, as per the RLNAD. The difference between the two products being the final form of the tablet administered (i.e., scored, chewable tablet vs. unscored, film-coated tablet).

***Dosage Strength.*** As noted above, Summit proposes to add two additional strengths: 12.5 and 37.5 mg phenylpropanolamine. The added strengths ensure that the same amount of active ingredient can be administered per dose when compared to the RLNAD (to account for the fact that Summit's proposed generic tablets are unscored).

***Bioequivalence.*** Summit is aware that for an ANADA directed to its proposed generic to be approved, Summit must demonstrate, *inter alia*, that its proposed generic is bioequivalent to the RLNAD. Summit intends to take all appropriate action toward demonstrating bioequivalence, including seeking and obtaining CVM concurrence on all relevant protocols.

*Legal Grounds*

Section 512(n)(3) of the FFDCA dictates that "[i]f a person wants to submit an abbreviated application for a new animal drug [...] whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug [...] such person shall submit a petition to the Secretary seeking permission to file such an application." *See also* 21 C.F.R. § 314.93.

## C. Environmental Impact

Summit claims that its proposed generic qualifies for a categorical exclusion under 21 C.F.R. § 25.30(h). Summit confirms that no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 C.F.R. § 25.21.

## D. Economic Impact

Summit will provide an economic impact statement if so required by the Commissioner.

## E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to Summit which are unfavorable to the Petition.

12/21/18

Stephen D. Organ, President, on behalf of: Dated

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