Via U.S. Priority Mail

2710
NOV 24 '20 PM4:12

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

Docket Management Branch,

The undersigned Harry B. Ray of Ray Law Firm, PLLC, submits this citizen petition to pursue approval of an Abbreviated New Animal Drug Application (ANADA) for Cefpodoxime Proxetil tablets containing 100mg and 200mg of cefpodoxime per tablet. The approved Reference Listed New Animal Drug (RLNAD) is SIMPLICEF® Tablets 100mg and 200mg, Zoetis Inc, NADA # 141-232. SIMPLICEF tablets are indicated for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus intermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasturella multocida*, and *Proteus mirabilis*.

The sponsor would like to propose an additional 50mg strength in addition to the 100mg and 200mg. This change does not alter or complicate the dosing scheme. The customary suitability petition is enclosed (Attachement-1).

Yours very truly,

Harry B. Ray
Ray Law Firm, PLLC
6150 Shallowford Road, Suite 105
Chattanooga, TN 37421
Phone: 423.693.0160
Fax: 423.693.0155
Email: hbr@hbrlaw.com

Food and Drug Administration
Dockets Management Branch
13 November 2020

Attachment-I Suitability Petition

Suitability Petition

Identification of Petitioner

This Suitability Petition is submitted by Harry B. Ray of Ray Law Firm, PLLC under the section 512(n)(3) of the Federal Food, Drug and Cosmetic Act.

Action Requested

Petitioner requests approval from the Food and Drug Administration to file an Abbreviated New Animal Drug Application (ANADA) for Cefpodoxime Proxetil Tablets with the addition of a 50mg tablet strength.

As shown below, all other claims, species, labeling, and conditions of use will remain unchanged from the RLNAD with the exception of the proposed additional strength.

	RLNAD	Proposed Generic Drug Product
Dosage Form	Tablets	Tablets
Route of Administration	Oral	Oral
Strength(s)	100mg and 200mg	50mg, 100mg and 200mg
Scoring on the tablets	Scored	Unscored
Species	Dogs	Dogs
Proposed Indications	SIMPLICEF tablets are indicated for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus intermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasturella multocida*, and *Proteus mirabilis*.	Cefpodoxime Proxetil Tablets are indicated for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus intermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasturella multocida*, and *Proteus mirabilis*.

In accordance with Section 512(n)(3) of the Federal Food, Drug and Cosmetic act, a petition is allowed for a new animal drug whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug. In this petition, we are

requesting the addition of a new 50 mg tablet strength. In addition, we are also requesting to remove the score line on the 100mg tablets and the 200mg tablets. The proposed new strength (50mg) and 100mg strength would fulfil the requirements for each dose to be administered as per the "Dosage and Administration section" of the package insert. These changes will not impact the safety and effectiveness of the drug.

The RLNAD product was approved with two strengths 100mg and 200mg. Each tablet size is scored. Upon evaluation of the dosing strategy for the RLNAD the petitioner determined that scoring does not have any benefit for the 200mg strength and addition of 50mg strength would suffice the needs of half tablet dosing of 100mg strength. This change will not impact the dosing regimen or dosage and administration of the RLNAD. A comparison of the dosing charts of RLNAD and proposed generic product are provided below.

RLNAD

Dosing Charts : For daily oral administration of Cefpodoxime at 5mg/kg (Table 1) and 10mg/kg (Table2)

Table 1. Dose Table for Cefpodoxime Tablets at 5mg/kg

Total Daily Dosage

Weight of Dog (lbs)						
Daily Dose		22	44	66	88	132
No. of 100mg tablets		0.5	1	1.5		1
No. of 200mg tablets					1	1

Weight of Dog (kgs)						
Daily Dose		10	20	30	40	60
No. of 100mg tablets		0.5	1	1.5		1
No. of 200mg tablets					1	1

Proposed Generic Product

Dosing Charts : For daily oral administration of Cefpodoxime at 5mg/kg (Table 1) and 10mg/kg (Table2)

Table 1. Dose Table for Cefpodoxime Tablets at 5mg/kg

Total Daily Dosage

Weight of Dog (lbs)						
Daily Dose		22	44	66	88	132
No. of 50mg tablets		1		1		
No. of 100mg tablets			1	1		1
No. of 200mg tablets					1	1

Weight of Dog (kgs)						
Daily Dose		10	20	30	40	60
No. of 50mg tablets		1		1		
No. of 100mg tablets			1	1		1

RLNAD

Table 2. Dose Table for Cefpodoxime Tablets at 10mg/kg

Total Daily Dosage

Weight of Dog (lbs)						
Daily Dose	11	22	44	66	88	132
No. of 100mg tablets	0.5	1		1		
No. of 200mg tablets			1	1	2	3

Weight of Dog (kgs)						
Daily Dose	5	10	20	30	40	60
No. of 100mg tablets	0.5	1		1		
No. of 200mg tablets			1	1	2	3

Proposed Generic Product

No. of 200mg tablets					1	1

Table 2. Dose Table for Cefpodoxime Tablets at 10mg/kg

Total Daily Dosage

Weight of Dog (lbs)						
Daily Dose	11	22	44	66	88	132
No. of 50mg tablets	1					
No. of 100mg tablets		1		1		
No. of 200mg tablets			1	1	2	3

Weight of Dog (kgs)						
Daily Dose	5	10	20	30	40	60
No. of 50mg tablets	1					
No. of 100mg tablets		1		1		
No. of 200mg tablets			1	1	2	3

Environmental Impact

In accordance with 21 CFR 25.15, Ray Law Firm, PLLC claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR 25.30(h). We confirm that to our knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21."

Economic Impact

The petitioner will, upon request by the commissioner, submit economic impact information, in accordance with 21 CFR § 10.30(b).

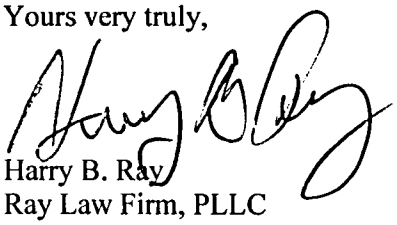
Certification

Food and Drug Administration
Dockets Management Branch
13 November 2020

The undersigned certifies that, to the best of our knowledge and belief, this petition includes all information upon which the petition relies, and that it includes representative data and information known to the petitioner which are unfavourable to the petition.

Should you have any questions please contact the undersigned.

Yours very truly,



Harry B. Ray
Ray Law Firm, PLLC
6150 Shallowford Road, Suite 105
Chattanooga, TN 37421
Phone: 423.693.0160
Fax: 423.693.0155
Email: hbr@hbrlaw.com