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

Re: **Deracoxib Solution**

SUITABILITY PETITION

Action Requested:
Aurora Pharmaceutical Inc, located at 1196 Hwy 3 South, Northfield, MN, 55057, submits this petition under Section 512(n)(3) of the Federal Food Drug and Cosmetic Act to request an FDA permission to file an abbreviated new animal drug application for generic animal drug **Deracoxib Solution 1.80% w/v**, that differs from the reference listed drug **Deramaxx™ (deracoxib) Chewable Tablets**, sponsored by Elanco US Inc. under NADA 141-203, in **dosage form** and **strength**.

The RLNAD Deramaxx is approved as chewable oral tablets for dogs with an active deracoxib content of 12 mg, 25 mg, 75 mg and 100 mg in half-scored round tablets packaged into 7, 30 and 90 count bottles. The proposed generic dosage form is an oral solution of deracoxib 1.80% w/v that will be packaged into multi-dose containers with recommendation to use oral dosing syringes allowing accurate dose delivery directly into dog's mouth.

The indications and dosages administration will be the same for the proposed generic product as the referenced drug.

Indication	Dosage, mg/lb*/day	Dosage, mg/kg*/day	Frequency	Maximum days
Osteoarthritis Pain and Inflammation	0.45-0.91	1-2	Single daily dose	As needed
Postoperative Orthopedic Pain and Inflammation	1.4-1.8	3-4	Single daily dose	Not to exceed 7 days
Postoperative Dental Pain and Inflammation	0.45-0.91	1-2	Single daily dose	For 3 days

*of body weight.

To the extent of our knowledge all excipients in the proposed generic formulation are already used in other approved oral products for dogs. This fact will be concurred with FDA prior to bioequivalence study.

All patents and marketing exclusivities listed for Deramaxx have expired.

Statement of Grounds:
The proposed generic copy will utilize the same active deracoxib as RLNAD. The route of administration (oral) is the same. Recommended dosages are not changed. The justification for the proposed change of the dosage form and strength is convenience to use a multi-dose packaging and ease of exact dose administration.

Environmental Impact:
In accordance with 21 CFR 25.15, Aurora Pharmaceutical, Inc. 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:
An economic impact analysis will be provided if requested after review of this petition.

Labeling:
General labeling information for the proposed generic Deracoxib Solution 1.80% w/v will be essentially the same as the reference listed drug Deramaxx™ Chewable Tablets labeling (enclosed), except the following changes:

- proprietary name
- dosage form, strength and administration instructions
- palatability
- how supplied
- "manufactured by" information, NDC#, label ID and ANADA#

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 the petitioner that are unfavorable to the petition.

If you have questions concerning this petition or require additional information, please, contact me by e-mail agarbar@aurorapharmaceutical.com or at tel. 507-645-3221.

Sincerely,

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02/27/2020 09:39:48 am

Alina Garbar, PhD Date
RA Director
Aurora Pharmaceutical, Inc.
1196 Hwy 3 South
Northfield, MN 55057