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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Rockville, MD 20857

February 27, 2020

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

Sent via email to: agarbar@aurorapharmaceutical.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting 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 DeramaxxTM (deracoxib) Chewable Tablets, sponsored by Elanco US Inc. under NADA 141-203, in dosage form and strength was received by this office on 02/27/2020.

It has been assigned docket number FDA-2020-P-0963. 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,

Karen Malvin Supervisory Administrative Proceedings Officer Dockets Management Staff FDA/Office of Operations (OO)