



## DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
Rockville, MD 20857

October 20, 2020

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

Sent via email to: [agarbar@aurorapharmaceutical.com](mailto:agarbar@aurorapharmaceutical.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to submit an abbreviated new animal drug application (ANADA) for a generic firocoxib oral solution (0.9% w/v) for use in horses that differs from reference listed new animal drug (RLNAD) in both dosage form and strength was received by this office on 10/20/2020.

It was assigned docket number FDA-2020-P-2102. 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 Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)