**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Rockville, MD 20857

January 30, 2020

Nathan A. Beaver
Foley & Lardner LLP
3000 K Street, N.W. Suite 500
Washington, D.C. 20007-5143

*Sent via email to:* nbeaver@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting not approve any abbreviated new drug application ("ANDA") for any generic version or other pharmaceutical alternative of ALINIA® (nitazoxanide) tablets ("Alinia® Tablets"), for oral use and ALINIA® (nitazoxanide) for oral suspension ("Alinia® Oral Suspension") (collectively "Alinia®") unless and until the applicant satisfies all of the conditions set forth in this petition was received by this office on 01/30/2020.

It was assigned docket number FDA-2020-P-0513. 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
Digitally signed by Dynna Bigby
Date: 2020.01.31 16:41:25 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)