



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 04, 2020

Nathan A. Beaver
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Sent via email to: nbeaver@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA not to approve any ANDA citing Alinia as the reference listed drug ("RLD") unless the applicant conducts:

- (1) bioequivalence studies of both active metabolites, tizoxanide and tizoxanide glucuronide, in plasma under fasted and fed conditions;
- (2) bioequivalence studies with clinical endpoints (regardless of whether the proposed generic product is quantitatively and qualitatively the same as the RLD); and
- (3) two bioequivalence studies with clinical endpoints – one in subjects with *G. lamblia* and another in subjects with *C. parvum*.

Your submission was received by this office on 02/04/2020 and it was assigned docket number FDA-2020-P-0599. 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)