DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 27, 2020

Nathan Beaver
Regulatory Counsel
Romark Laboratories, L.C.
3000 K Street, N.W., Suite 500
Washington, DC 20007-5143

Sent via email to: nbeaver@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA not 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 01/24/2020, and it was assigned docket number FDA-2020-P-0436. 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: 2020.01.27 14:55:29 -05'00'

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