FOLEY & LARDNER LLP

FOLEY & LARDNER LLP
ATTORNEYS AT LAW
WASHINGTON HARBOUR
3000 K STREET, N.W., SUITE 600
WASHINGTON, D.C. 20007-5143
202.672.5300 TEL
202.672.5399 FAX
www.foley.com
WRITER'S DIRECT LINE
202.295.4039
nbeaver@foley.com EMAIL

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VIA REGULATIONS.GOV

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5360 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Withdrawal of Citizen Petition; Docket No. FDA 2020-P-0513

Dear Sir or Madam:

Petitioner requests withdrawal of the above-referenced citizen petition requesting that the Commissioner of Food and Drugs 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. Consequently, a formal response to Docket No. FDA-2020-P-0513 is no longer necessary.

Sincerely yours,

Nathan A. Beaver
Regulatory Counsel to
Romark Laboratories, L.C.