U.S. FOOD & DRUG ADMINISTRATION

Nathan A, Beaver, Esq
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Washington, DC 20007-5143

Re: Docket No. FDA-2020-P-0599

July 28, 2020

Dear Mr. Beaver:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on February 4, 2020 and submitted on behalf of Romark Laboratories. Your petition requests that the Agency not approve any Abbreviated New Drug Applications referencing Alina (nitazoxanide) as the reference listed drug unless the applicant conducts bioequivalence studies as detailed in the citizen petition. It also requests that FDA revise product specific guidance for nitazoxanide.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.07.28 09:11:55 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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