



Gretchen DuBeau
Executive and Legal Director
Alliance for Natural Health USA
1011 East Jefferson Street
Suite 204
Charlottesville, VA 22902

December 3, 2020

Re: Docket No. FDA-2020-P-1540

Dear Ms. DuBeau:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 10, 2020 and submitted on behalf of the Alliance for Natural Health USA. Your petition requests that the Agency issue a regulation mandating that:

[a]ll makers of Proton Pump Inhibitor (PPI) medications for humans expand the existing warnings on their product's labeling to include warning about increased risk of pneumonia.

(Petition at 2).

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
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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research