DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 11, 2020

Gretchen DuBeau
Executive and Legal Director
Alliance for Natural Health USA
1011 E Jefferson St.
Ste 204
Charlottesville, VA 22902

Sent via email to: gretchen@anh-usa.org

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to issue a regulation that all 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 was received by this office on 06/10/2020.

It was assigned docket number FDA-2020-P-1540. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.06.11 10:10:02 -04'00'

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