July 15, 2022

Gretchen DuBeau, Esq.
Alliance for Natural Health USA
94 Landfill Road
Edinburg, VA 22824

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

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to issue a regulation that all makers of proton pump inhibitors (PPIs) add a black box warning to their product's labeling warning of the link between taking PPIs and the risk of developing dementia was received and processed under CFR 10.30 by this office on 07/15/2022.

It was assigned docket number FDA-2022-P-1576. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S

Digitally signed by Karen P. Malvin -S
Date: 2022.07.15 15:21:28 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)