



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 31, 2020

A. Neal Seth
David T. Read
Wiley Rein, LLP
1776 K Street N.W.
Washington, DC 20006

Sent via email to: nseth@wiley.law

Dear Petitioner:

Your Petition for Stay of Action (PSA) to the Commissioner of Food and Drug Administration requesting the FDA to immediately stay the effective date of the approval of NDA22122/S-14 and that the stay of approval remain in place no less than thirty days after the Agency issues a response, constituting final agency action, to the citizen petition submitted pursuant to 21 CFR 10.30 that accompanies this petition for stay of action was received by this office on 03/30/2020.

It was assigned docket number FDA-2020-P-1239. 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 Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)