



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 25, 2020

Michael Edney
Steptoe & Johnson LLP
1330 Connecticut Avenue, NW
Washington, DC 20036

Sent via email to: medney@steptoe.com

Dear Petitioner:

Your petition for Stay of Action (PSA) to the Commissioner of Food and Drug Administration requesting that the FDA stay of the pending May 12, 2020 deadline for substantial equivalence reports required as a result of the Final Deeming Rule published in the Federal Register on May 10, 2016 at 81 Fed. Reg. 28,973 was received by this office on 03/24/2020.

It was assigned docket number FDA-2020-P-1205. 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,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)