



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 24, 2020

Max D. Stern
Todd & Weld, LLP
One Federal Street
Boston, MA 02110

Sent via email to: mdstern@toddweld.com

Dear Petitioner:

Your petition for Stay of Action (PSA) to the Commissioner of Food and Drug Administration requesting that the FDA stay both of the two effective dates of FDA's final regulation banning electrical stimulation devices used to treat self-injurious or aggressive behavior (the "Final Rule" or "Ban") published in the Federal Register on March 6, 2020 at 85 Fed. Reg. 13312 was received by this office on 03/23/2020.

It was assigned docket number FDA-2020-P-1181. 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)

CC: Alexandra H. Deal – adeal@pbdlaw.com