



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 2085

March 23, 2020

Michael P. Flammia
ECKERT SEAMANS CHERIN & MELLOTT, LLC
Two International Place, 16th Floor
Boston, MA 02110
mflammia@eckertseamans.com

Dear Petitioners:

Your Petition for Stay of Action (PSA) to the Commissioner of Food and Drug Administration requesting that the FDA must immediately and indefinitely stay both of the two effective dates for its final regulation banning electrical stimulation devices ("ESDs") used to treat self-injurious behavior ("SIB") or aggressive behavior ("AB") which was received by this office on 03/23/2020.

It was assigned docket number FDA-2020-P-1166. 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: Christian B.W. Stephens
Matthew D. Rodgers
elongosz@eckertseamans.com