DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 1, 2019

Brian J. Malkin, Esq.
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Sent via email to: brian.malkin@arentfox.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

(1) The FDA should require Neurelis to conduct a bridging study comparing Valtoco to Diastat in patients, demonstrating comparable exposure to support approval of its 505(b)(2) NDA.

(2) The FDA should require Neurelis to conduct a food effect study for Valtoco that will allow for adequate labeling to address the low Cmax and curiously delayed Tmax that suggests the product is primarily swallowed and absorbed through the GI tract, not nasally.

(3) The FDA should determine that Valtoco is not clinically superior to nor offers a major contribution to patient care when compared to Diastat.

Your submission was received by this office on 11/01/2019, and it was assigned docket number FDA-2019-P-5121. 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 Kennard -S
Digitally signed by Karen Kennard -S
Date: 2019.11.04 11:12:40 -05'00'

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