DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 6, 2019

Nayna Daptardar
Sun Pharmaceutical Industries Limited
Sun House, Plot No. 201 B/1, Western Express Highway
Goregaon (E), Mumbai – 400063
Maharashtra, INDIA

Sent via email: Nayna.Daptardar@sunpharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA determine that the drug product Levetiracetam in Sodium Chloride Injection, 2.5 mg/mL (250 mg/100 mL), is suitable for submission as an ANDA. The proposed ANDA includes Levetiracetam in Sodium Chloride Injection, 5 mg/mL, 10 mg/mL and 15 mg/mL, 100 mL infusion bag, corresponding to the approved dosage strengths of the RLD, along with an additional strength of 2.5 mg/mL (250 mg/100 mL). Therefore Sun seeks permission to file an ANDA that includes a strength that differs from that of the listed drug in addition to the approved dosage strengths was received by this office on 12/06/2019.

It was assigned docket number FDA-2019-P-5760. 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
Digitally signed by Dynna Bigby
Date: 2019.12.06 11:47:36 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)