Sun Pharmaceutical Industries Limited
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July 7, 2021

ELECTRONIC SUBMISSION VIA REGULATIONS.GOV
CITIZEN PETITION
ANDA SUITABILITY PETITION

Re: Amendment to Suitability Petition
Levetiracetam in Sodium Chloride Injection, 2.5 mg/mL (250 mg/100 mL)
Docket No. FDA-2019-P-5760

Dear Sir/Madam,

Sun Pharmaceutical Industries Limited submitted this suitability petition, pursuant to section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 C.F.R. § 10.20, § 10.30, and § 314.93 on December 06, 2019 requesting the Commissioner of the Food and Drug Administration to determine that the drug product, Levetiracetam in Sodium Chloride Injection, 250 mg/100 mL (2.5 mg/mL) is suitable for consideration in an abbreviated new drug application (ANDA).

Reference is made to information request dated March 17, 2021, wherein the Agency requested Sun Pharmaceutical Industries Limited to clarify its intention with subject suitability petition, taking into consideration approval of 250 mg/50 mL strength for RLD on December 14, 2020 and accordingly either update the petition to request change in concentration or submit request for a withdrawal. As Sun intends to request a change in strength (2.5 mg/mL), petition has been updated accordingly.

A. Action Requested

Sun Pharmaceutical Industries Limited requests that the Commissioner of the Food and Drug Administration determine that the drug product Levetiracetam in Sodium Chloride Injection, 250 mg/100 mL (2.5 mg/mL), is suitable for submission as an ANDA. The proposed 250 mg/100 mL (2.5 mg/mL) strength differs from the RLD dosage strength of 250 mg/50 mL (5 mg/mL). Therefore, Sun seeks permission to file this strength in an ANDA in addition to the approved dosage strengths 500 mg/100 mL (5 mg/mL), 1,000 mg/100 mL (10 mg/mL) and 1,500 mg/100 mL (15 mg/mL).

The reference listed drug product (RLD), upon which this petition is based, is Levetiracetam in Sodium Chloride Injection, 250 mg/50 mL (5 mg/mL), 500 mg/100 mL (5 mg/mL), 1,000 mg/100 mL (10 mg/mL) and 1,500 mg/100 mL (15 mg/mL) in an infusion bag, NDA 202543 held by HQ Speciality Pharma LLC. This approved NDA also recommends for Levetiracetam in Sodium Chloride Injection in the 250 mg to 750 mg dosage strengths. Hence Sun Pharmaceutical Industries Limited is proposing a strength of 250 mg/100 mL (2.5 mg/mL) which differs from the approved RLD strength of 250 mg/50 mL (5 mg/mL); however there is no change in total drug content of 250 mg per infusion bag to achieve the required doses.

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B. Statement of Grounds

The Federal, Food and Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

Levetiracetam in Sodium Chloride Injection is an antiepileptic drug available as a clear, colorless, sterile solution for intravenous administration available in four strengths, 250 mg/50 mL (5 mg/mL), 500 mg/100 mL (5 mg/mL), 1,000 mg/100 mL (10 mg/mL) and 1,500 mg/100 mL (15 mg/mL) in a single dose 100 mL dual port bag with an aluminium over wrap. See the copy of the page from current electronic edition of the *Approved Drug Products with Therapeutic Equivalence Evaluation* (**Attachment 1**). The proposed drug product in the ANDA is identical to the RLD with regards to, active ingredient, excipients, route of administration, indication and the three approved dosage strengths, however a drug product strength of 250 mg/100 mL (2.5 mg/mL) instead of 250 mg/50 mL (5 mg/mL) shall be provided to facilitate dose adjustment as indicated in the RLD's approved labeling.

For adult patients with impaired renal function, **t**he current approved labeling states that dosing must be individualized according to the patient's renal function status. For patients with moderate and severe impaired renal function the recommended doses and adjustment for dose for adults are 250-750 mg and 250-500 mg respectively. The RLD provides the said dosage as 250 mg/50 mL (5 mg/mL) strength for the above mentioned patient group; whereas Sun Pharmaceutical Industries Limited intends to provide the said dosage as the 250 mg/100 mL (2.5 mg/mL) strength.

There are no proposed changes in the labeling with the exception of change of proposed strength 250 mg/100 mL (2.5 mg/mL) sought in this petition. The uses, indication, warning and direction of use will remain the same as that of RLD. Draft labeling for the proposed product is included in **Attachment 2** and current RLD's approved labeling is provided in **Attachment 3**.

Therefore, the petitioner's request for the Commissioner to find that change in strength i.e. 250 mg/100 mL (2.5 mg/mL) for Levetiracetam in Sodium Chloride Injection should raise no question of safety or effectiveness, and Agency should approve the petition.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that economic impact evaluation is applicable in this case, but will agree such an analysis if requested by the agency.

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E. Certification

Sun Pharmaceutical Industries Limited certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavourable to the petition.

Please direct any questions or comments regarding this submission to the attention of Nayna Daptardar, Senior General Manager, Regulatory & Business Continuity, Phone: +91-265-6615500, Fax: +91-265-2354897, Email: Nayna.Daptardar@sunpharma.com.

Sincerely,

Nayna Daptardar

Digitally signed by Nayna Daptardar
DN: c=IN, st=Gujarat, l=Vadodara, o=Sun Pharmaceutical Industries Limited, cn=Nayna Daptardar, email=nayna.daptardar@sunpharma.com
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Nayna Daptardar
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Attachments:

1. Approved Drug products with Therapeutic Equivalence Evaluation, accessed May 05, 2021

2. Proposed Prescribing Information for Levetiracetam in Sodium Chloride Injection, 2.5 mg/mL, 5 mg/mL, 10 mg/mL and 15 mg/mL

3. Reference Listed Drug Prescribing Information for Levetiracetam in Sodium Chloride Injection

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