Sun Pharmaceutical Industries Limited
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December 06, 2019

ELECTRONIC SUBMISSION VIA REGULATIONS.GOV
CITIZEN PETITION
ANDA SUITABILITY PETITION

Dear Sir/Madam,

Sun Pharmaceutical Industries Limited submits 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 requesting the Commissioner of the Food and Drug Administration to determine that the drug product, Levetiracetam in Sodium Chloride Injection, 2.5 mg/mL (250 mg/100 mL) is suitable for consideration in an abbreviated new drug application (ANDA).

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, 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.

The listed reference drug product (RLD), upon which this petition is based, is Levetiracetam in Sodium Chloride Injection, 5 mg/mL, 10 mg/mL and 15 mg/mL, 100 mL 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. However, to achieve the required doses (e.g. 250 mg and 750 mg), RLD is using aseptic technique for withdrawal of the required doses from available product strengths. Hence, Sun Pharmaceutical Industries Limited is proposing a change in strength with total drug content of 250 mg in a 100 mL infusion bag to achieve required doses. Note there is no change in existing drug concentration but only an addition of strength to achieve the required doses.

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 three strengths 5 mg/mL, 10 mg/mL and 15 mg/mL in a single dose 100 mL dual port bag with an aluminium over wrap. See the copy of the page from

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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 an additional strength of 2.5 mg/mL (250 mg/100 mL) shall also be provided to facilitate dose adjustment 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 moderate and severe group recommended doses and adjustment for dose for adults are 250-750 mg and 250-500 mg respectively. For 250 mg and 750 mg doses which are not achievable with the available product strengths, RLD package insert instructs to withdraw appropriate dose from an intact commercial bag and place the measured dose in a separate empty, sterile infusion bag using aseptic technique. Thus the 2.5 mg/mL (250 mg/100 mL) strength would provide a more convenient dosage package to provide the recommended dose and also reduce the risk of medication error and microbiological contamination.

There are no proposed changes in the labeling with the exception of the obvious changes in strength 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 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. change in total drug content, 250 mg/100 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.

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 Affairs, Phone: +91-265-6615500, Fax: +91-265-2354897, Email: Nayna.Daptardar@sunpharma.com.

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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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Attachments:

1. Approved Drug products with Therapeutic Equivalence Evaluation, accessed December 06, 2019

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