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

Sent via email to: Nayna.Daptardar@sunpharma.com

Docket No. FDA-2019-P-5760

Dear Nayna Daptardar:

This is in response to your petition received on December 6, 2019, by the U.S. Food and Drug Administration (FDA or Agency) and your amendment dated July 7, 2021, requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Levetiracetam in Sodium Chloride Injection, 250 mg/100 mL (2.5 mg/mL) single-dose bags. The listed drug product to which you refer in your petition is Levetiracetam in Sodium Chloride Injection, 250 mg/50 mL (5 mg/mL); 500 mg/100 mL (5 mg/mL); 1000 mg/100 mL (10 mg/mL); 1500 mg/100 mL (15 mg/mL) single-dose bags, approved under NDA 202543 and held by HQ Specialty Pharma Corp.

Your request involves a change in strength (concentration) from that of the listed drug product (i.e., from 250 mg/50 mL (5 mg/mL); 500 mg/100 mL (5 mg/mL); 1000 mg/100 mL (10 mg/mL); 1500 mg/100 mL (15 mg/mL) single-dose bags to 250 mg/100 mL (2.5 mg/mL) single-dose bags). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act. However, for the reasons explained below, the Agency denies your request.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, that any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(iv).

The Agency has determined that your proposed change in strength (concentration) raises questions of safety and effectiveness. The use of a more dilute Levetiracetam in Sodium Chloride Injection Solution has no apparent benefit for patients with renal insufficiency and would give patients twice the fluid volume sodium load as compared to the available RLD product (Levetiracetam in Sodium Chloride Injection, 250 mg/50 mL (5 mg/mL)). This would be a concern for patients with moderate to severe impaired renal function. Additionally, the increase in sodium would not be acceptable in a patient on sodium restriction for chronic kidney disease. The proposed new concentration for this drug product could have meaningful clinical consequences and could negatively impact patient care. Finally, there is also potential for confusion from having two products with two different concentrations on the market for no apparent clinical benefit.

Therefore, this petition is being denied because significant labeling changes would be needed to address the newly introduced safety or effectiveness problem posed by the proposed strength (concentration), which differs from the listed drug product. Please contact the Office of New Drugs, Office of Neuroscience, Division of Neurology II at (301) 796-2250, if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William H. Chong -S

Digitally signed by William H. Chong -S
Date: 2024.10.25 07:55:37 -04'00'

William Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Iilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research