February 26th, 2019

Division of Dockets Management
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR § 10.20 and § 10.30, as provided for in 21 CFR §314.93, and section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product Lacosamide Granules for Oral Solution, 10 mg/mL is suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petition is submitted for a change in dosage form of the drug product from "oral solution" to "granules for oral solution". The reference listed drug product (RLD) upon which this petition is based is VIMPAT® (lacosamide) Oral Solution 10 mg/mL, approved under NDA 022255 held by UCB INC. Lacosamide will be marketed as granules for oral solution in the dosage strength of 10 mg/mL. The drug, the route of administration and the recommendations for use are the same as the RLD product. The proposed product would differ only in dosage form from the UCB INC company marketed product.

The proposed drug product is expected to demonstrate bioequivalence to the RLD. Data will be submitted along with the ANDA for review of the agency, in case if this petition is approved.

B. Statement of Grounds

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

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The RLD, VIMPAT® (lacosamide) Oral Solution is available as 10 mg/mL oral solution supplied in 200 mL and 465 mL bottles. The proposed drug product is intended for use as 10 mg/mL oral solution after reconstitution, supplied as 2000 mg and 4650 mg granules in 200 mL and 465 mL bottles respectively. The proposed product will provide an alternative to oral solution for patients who have difficulty in swallowing solid oral dosage form, which facilitates ease of carrying and does not have the inherent stability problems associated with liquid formulations.

The proposed drug product will differ only in dosage form. The indications, strength, route of administration, intended patient population and recommendations for use will remain the same as that of the RLD. There are no proposed changes in labeling with the exception of the change in dosage form sought in this petition. Therefore, there will be no difference in the safety and efficacy of the proposed Lacosamide Granules, for Oral Solution.

The approved labeling for the listed drug, UCB INC's VIMPAT® (lacosamide) Oral Solution, is provided in Attachment A. The proposed package insert for Lacosamide Granules, for Oral Solution is provided in Attachment B.

C. Pediatric Use Information

As the package insert of VIMPAT® (lacosamide) Oral Solution contains adequate dosing and administration information for the pediatric population, no additional pediatric studies are required as a result of this suitability petition.

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR § 25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such analysis if requested by the agency.

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F. Certification

The under signed certifies that to the best of his/her knowledge, the 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 unfavorable to the petition.

Yours sincerely

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