May 5, 2022

Via Electronic Submission

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HF A-305)
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam:

RegCon Solutions, LLC (the "Petitioner") hereby submits this Citizen Petition (ANDA Suitability petition) under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 314.93 & 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration allow the submission and filing of an abbreviated new drug application (ANDA) for Lacosamide Injection USP 100mg/10mL (10mg/mL).

A. Action Requested

The Petitioner hereby submits a suitability petition under 21 CFR section 314.93, requesting the Commissioner of FDA to make a determination that Lacosamide Injection USP 100mg/10mL (10mg/mL) is suitable for submission as an ANDA.

The listed reference drug product (RLD), upon which this petition is based, is VIMPAT® (lacosamide) injection 200mg/20mL (10mg/mL) by UCB INC. NDA# N022254.

Currently the RLD VIMPAT® is available as 20 ml vial (total drug content 200mg/20mL). Therefore, the petitioner seeks a change in strength, from 200 mg/20 mL single-dose vial to 100 mg/10 mL single-dose vial.

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 strength and or dosage form from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, VIMPAT® by UCB INC. is an injection product containing Lacosamide Injection 200mg/20mL (10mg/mL). Please refer to listing in the current electronic edition of Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 1) and the last approved labeling

(Attachment 2). The proposed drug product represents change in total drug content and proposes the 100 mg/10 mL (10 mg/mL) strength in single-dose vials. Thus, this petition is seeking a change in strength (total drug content) from 200 mg/20 mL single-dose vials to 100 mg/10mL single dose vials.

Please note that the proposed changes in strength represent dosage strengths that are clearly contemplated in the labeling of the RLD, VIMPAT®. According to the Dosage and Administration in the current approved package insert for VIMPAT®, recommended dosage regimen is dependent upon body weight. Dosage should be increased based on clinical response and tolerability.

Table 1: Recommended Dosages for Partial-Onset Seizures (Monotherapy or Adjunctive Therapy) in Patients 1 Month and Older, and for Primary Generalized Tonic-Clonic Seizures (Adjunctive Therapy) in Patients 4 Years of Age and Older*

Age and Body Weight	Initial Dosage	Titration Regimen	Maintenance Dosage
Adults (17 years and older)	**Monotherapy**:** 100 mg twice daily (200 mg per day) **Adjunctive Therapy:** 50 mg twice daily (100 mg per day) **Alternate Initial Dosage:** 200 mg single loading dose, followed 12 hours later by 100 mg twice daily	Increase by 50 mg twice daily (100 mg per day) every week	**Monotherapy**:** 150 mg to 200 mg twice daily (300 mg to 400 mg per day) **Adjunctive Therapy:** 100 mg to 200 mg twice daily (200 mg to 400 mg per day)
Pediatric patients weighing 50 kg or more	50 mg twice daily (100 mg per day)	Increase by 50 mg twice daily (100 mg per day) every week	**Monotherapy**:** 150 mg to 200 mg twice daily (300 mg to 400 mg per day) **Adjunctive Therapy:** 100 mg to 200 mg twice daily (200 mg to 400 mg per day)
Pediatric patients weighing 30 kg to less than 50 kg	1 mg/kg twice daily (2 mg/kg/day)	Increase by 1 mg/kg twice daily (2 mg/kg/day) every week	2 mg/kg to 4 mg/kg twice daily (4 mg/kg/day to 8 mg/kg/day)
Pediatric patients weighing 11 kg to less than 30 kg	1 mg/kg twice daily (2 mg/kg/day)	Increase by 1 mg/kg twice daily (2 mg/kg/day) every week	3 mg/kg to 6 mg/kg twice daily (6 mg/kg/day to 12 mg/kg/day)
Pediatric patients weighing 6 kg to less than 11 kg ±			
Pediatric patients weighing less than 6 kg ±	**Intravenous:** 0.66 mg/kg three times daily (2 mg/kg/day)	**Intravenous:** Increase by 0.66 mg/kg three times daily (2 mg/kg/day) every week	**Intravenous:** 2.5 mg/kg to 5 mg/kg three times daily (7.5 mg/kg/day to 15 mg/kg/day)

Age and Body Weight	Initial Dosage	Titration Regimen	Maintenance Dosage
	Oral: 1 mg/kg twice daily (2 mg/kg/day)	**Oral:** Increase by 1 mg/kg twice daily (2 mg/kg/day) every week	**Oral:** 3.75 mg/kg to 7.5 mg/kg twice daily (7.5 mg/kg/day to 15 mg/kg/day)
* When not specified, the dosage is the same for monotherapy for partial-onset seizures and adjunctive therapy for partial-onset seizures or primary generalized tonic-clonic seizures. Oral and intravenous dosages are the same unless specified. ** Monotherapy for partial-onset seizures only ± Indicated only for partial-onset seizures.			

Lacosamide Injection may be initiated in adult patients with a single loading dose of 200 mg, followed approximately 12 hours later by 100 mg twice daily (200 mg per day). The maintenance dose regimen should be continued for one week. Lacosamide Injection can then be titrated as recommended in table 1.

Lacosamide injection is for single-dose only and any unused portion of VIMPAT injection should be discarded. Lacosamide Injection can be administered intravenously without further dilution or may be mixed with diluents as listed in RLD label (attachment 2). The diluted solution should not be stored for more than 4 hours at room temperature.

A 100mg/10mL single-dose presentation would provide a sufficient amount of drug to meet dosage recommendation for loading dose (2 x 100mg/10 ml vial) regimen and maintenance dosage of Lacosamide. Proposed strength is appropriate for use in maintenance dosing of Lacosamide after initiating a single loading dose of 200mg and will eliminate drug product wastage.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition, administrative information and container closure. The uses, indications, warnings and directions for use will remain the same as that of the RLD. The RLD's approved labeling is provided in Attachment 2.

Therefore, the petitioner's request for the Commissioner to find that a change in strength (i.e., a change in total drug content from 200 mg/20mL to 100 mg/10mL for Lacosamide Injection) should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

D. Economic Impact Statement

Pursuant to 21 C.F.R. § 10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that to the best of 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 unfavorable to the petition.

Respectfully submitted,

Frederik Defesche
President,
RegCon Solutions, LLC,

Attachments:

1. Relevant copy of the page from the current edition of the electronic Approved Drug Products with Therapeutic Equivalence Evaluations

2. Labeling for VIMPAT® (lacosamide) injection 200mg/20mL (10mg/mL) by UCB INC.

3. Draft Insert Labeling Proposed for Lacosamide Injection 100mg/10mL