

NDA 022253/S-049
 NDA 022254/S-039
 NDA 022255/S-031

SUPPLEMENT APPROVAL

UCB, Inc.
 Attention: Kelly Roney, Ph.D., RAC
 US Regulatory Science Team Lead, Epilepsies America
 4000 Paramount Parkway, Suite 200
 Morrisville, NC 27560

Dear Dr. Roney:

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

| Application | Product Name | Submitted on: | Received on: |
|------------------|-----------------------------------|-------------------|-------------------|
| NDA 022253/S-049 | Vimpat (lacosamide) Tablets | December 15, 2020 | December 15, 2020 |
| NDA 022254/S-039 | Vimpat (lacosamide) Injection | December 15, 2020 | December 15, 2020 |
| NDA 022255/S-031 | Vimpat (lacosamide) Oral Solution | December 15, 2020 | December 15, 2020 |

These Prior Approval supplements propose:

The use of lacosamide for oral and intravenous monotherapy and adjunctive therapy in the treatment of partial onset seizure patients ≥1 month to <4 years of age. Increase of in-use shelf-life for oral solution from 7-weeks to 6-months to support proposed indication in partial onset seizure patients ≥1 month to <4 years of age.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

Submit the final printed container label that is identical to the container label submitted on June 8, 2021, as soon as it is available, but no more than 30 days after it is printed. Please submit this labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA 022255/S-031.**” Approval of this submission by FDA is not required before the labeling is used.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We refer to your sNDAs submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vimpat (lacosamide) Tablets, Vimpat (lacosamide) Injection, and Vimpat (lacosamide) Oral Solution.

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

We have received your submission dated December 15, 2020, containing the final reports for the following postmarketing requirements listed in the October 28, 2008, and August 29, 2014, approval letters.

- 3288-1 A prospective, randomized, controlled, double-blind, efficacy, pharmacokinetics and safety study of the adjunctive use of lacosamide for the treatment of partial onset seizures in children ages 1 month to < 4 years. The primary efficacy endpoint must examine seizure frequency based upon Video/EEG data. Safety must be evaluated during the controlled study and with a long-term safety extension. At least 50% of children in the study should be < 2 years old. A pharmacokinetic analysis must also be performed to determine a dosing regimen for the monotherapy use of lacosamide in pediatric patients ages 1 month to < 4 years of age.
- 3293-1 Deferred pediatric studies under PREA for the treatment of partial onset seizures in pediatric patients ages 1 month to < 4 years.
- 2774-1 A safety study of replacement of oral dosing with intravenous dosing administered over 30 to 60 minutes in pediatric patients \geq 1 month to < 17 years of age with partial onset seizures. If safety is acceptable, a replacement study at a faster rate of infusion (15 minutes) must be conducted in this population. Sparse PK samples must be collected to evaluate the pharmacokinetics of lacosamide and its metabolite using PPK approach in this population.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the October 28, 2008, and August 29, 2014, approval letters that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Stephanie N. Parncutt, M.H.A., Senior Regulatory Health Project Manager, at (301) 796-4098 or email her at Stephanie.Parncutt@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Nick Kozauer, M.D.
Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NICHOLAS A KOZAUER
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