NDA 022253/S-050
NDA 022254/S-040
NDA 022255/S-032

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Lara Duffney, Ph.D., RAC
Regulatory Scientist
4000 Paramount Parkway, Suite 200
Morrisville, NC 27560

Dear Dr. Duffney:

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-050	Vimpat (lacosamide) Tablets	June 30, 2022	June 30, 2022
NDA 022254/S-040	Vimpat (lacosamide) Injection	June 30, 2022	June 30, 2022
NDA 022255/S-032	Vimpat (lacosamide) Oral Solution	June 30, 2022	June 30, 2022
These Prior Approval supplements propose:			
The use of alternate initial dosing (loading dose) for initiation of lacosamide treatment in partial onset seizure patients ≥1 month to <17 years of age and in primary generalized tonic-clonic seizure patients ≥4 to <17 years, across all formulations.			

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 Effected" (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 these NDAs, 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 these supplemental applications, 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).

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.

We have received your submissions dated December 15, 2020, and June 30, 2022, containing the final reports for the following postmarketing requirements listed in the November 16, 2020, and August 29, 2014, approval letters.

3957-1 A study that will examine safety and tolerability of an oral loading dose of Vimpat (lacosamide) that will allow a more rapid achievement of the final recommended therapeutic dose in pediatric patients 4 to <17 years of age.

3957-2 A study that will examine safety and tolerability of an intravenous loading

[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.

dose of Vimpat (lacosamide) that will allow a more rapid achievement of steady-state exposures of the final recommended therapeutic dose in pediatric patients 4 to <17 years of age.

2774-2 A study that will examine safety and tolerability of an oral loading dose that will allow a more rapid achievement of the final recommended therapeutic dose in pediatric patients ≥ 1 month to < 17 years of age.

2774-3 A study that will examine safety and tolerability of an intravenous loading dose that will allow a more rapid achievement of steady-state exposures of the final recommended therapeutic dose in pediatric patients ≥ 1 month to < 17 years of age.

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

We remind you that there are postmarketing requirements listed in the November 3, 2017, approval letter, and June 7, 2021, postapproval postmarketing requirement letter 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]

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]

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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}

Paul R. Lee, MD, PhD
Acting Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

PAUL R LEE
04/28/2023 10:04:51 AM