NDA 22253/S-46 and S-48
NDA 22254/S-36 and S-38
NDA 22255/S-27 and S-30

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

UCB, Inc.
Attention: Justin Franklin, PharmD
US Regulatory Science Lead
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Dr. Franklin:

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

Application	Product	Submitted and received on:	Provides for:
NDA 22253/S-046 NDA 22254/S-036 NDA 22255/S-027	Vimpat (lacosamide) tablets Vimpat (lacosamide) injection Vimpat (lacosamide) oral solution	January 16, 2020	The addition of a new indication for adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.
NDA 22254/S-038	Vimpat (lacosamide) injection	April 30, 2020	The expansion of the intravenous (iv) use of lacosamide for the treatment of partial onset seizures in patients 4 to less than 17 years of age.

NDA 22253/S-048 NDA 22255/S-030	Vimpat (lacosamide) tablets Vimpat (lacosamide) oral solution	April 30, 2020	The incorporation (by cross-reference) of labeling revisions provided in NDA 022254/S-038 into the tablets and oral solution labeling as the approved labeling for all three NDAs is contained with the same full prescribing information.

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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

[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.

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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Primary Generalized Tonic-Clonic Seizures (PGTCS) Supplements (NDA 22253/S-046, NDA 22254/S-036, and NDA 22255/S-027):

We are waiving the pediatric study requirement for less than 4 years of age because necessary studies are impossible or highly impracticable. This is because the diagnosis is rare prior to 6 years of age and, when it is diagnosed prior to age 4 years of age, it is generally more responsive to currently available treatments, and does not become refractory until later in its course.

We are deferring submission of your pediatric studies of the use of oral and intravenous loading doses for ages 4 to less than 17 years for this application because this product is ready for approval for use in adults and these pediatric studies have not been completed. Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

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.

Study Completion:	09/2020
Final Report Submission:	03/2021

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

Study Completion: 09/2020
Final Report Submission: 03/2021

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

This product is appropriately labeled for use in ages 4 years and older for adjunctive therapy in the treatment of PGTCS for all Vimpat formulations.

Partial Onset Seizure (POS) Supplements (NDA 22253/S-048, NDA 22254/S-038, and NDA 22255/S-030):

We note that you have fulfilled the pediatric study requirement for ages 4 to less than 17 years for Vimpat (lacosamide) injection.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We refer to your sNDA submitted under section 505(b) of the FDCA for Vimpat (lacosamide) injection (NDA 22254/S-038).

We have received your submission dated April 30, 2020, containing the final report for the following postmarketing requirement listed in the November 3, 2017, approval letter.

3293-2 Deferred pediatric studies under PREA for the treatment of partial-onset seizures in pediatric patients ages 4 years to <17 years.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the August 29, 2014, and November 3, 2017, 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]

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 Stephanie.Parncutt@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.