DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022253/S-026 & S-027
NDA 022254/S-019 & S-020
NDA 022255/S-012 & S-013

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Susan Tegtmeyer, M.S.
Associate Director, Regulatory Affairs
1950 Lake Park Drive,
Smyrna, Georgia 30080

Dear Ms. Tegtmeyer:

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-026	Vimpat (lacosamide) Tablets	July 31, 2013	August 1, 2013
NDA 022254/S-020	Vimpat (lacosamide) Injection	July 31, 2013	August 1, 2013
NDA 022255/S-013	Vimpat (lacosamide) Oral Solution	July 31, 2013	August 1, 2013
These supplements propose:			
The use of Vimpat as monotherapy (conversion to and initial) in the treatment of partial-onset seizures in patients with epilepsy age 17 years and older.			

Application	Product Name	Submitted on:	Received on:
NDA 022253/S-027	Vimpat (lacosamide) Tablets	July 31, 2013	August 1, 2013
NDA 022254/S-019	Vimpat (lacosamide) Injection	July 31, 2013	August 1, 2013
NDA 022255/S-012	Vimpat (lacosamide) Oral Solution	July 31, 2013	August 1, 2013
These supplements propose:			
1. The initiation of VIMPAT therapy with a loading dose (oral or intravenous) of 200 mg. 2. A lower limit of 15 minutes for the infusion duration.			

We acknowledge receipt of your amendments dated October 3, 2013; October 11, 2013; October 22, 2013; November 4, 2013; November 25, 2013; November 26, 2013; January 24, 2014; February 4, 2014; February 6, 2014; February 19, 2014; March 6, 2014; March 31, 2014; April 25, 2014; May 2, 2014; May 9, 2014; May 15, 2014; May 23, 2014; May 27, 2014; May 30, 2014; June 26, 2014; June 30, 2014; July 22, 2014, July 25, 2014; and August 7, 2014.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert 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 titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for ages 0 to 1 month because necessary studies are impossible or highly impracticable. This is because studies are challenging in children < 1month due to small number of patients and difficulty of diagnosis in this age group.

We are deferring submission of your pediatric studies for ages ≥ 1 month to < 17 years for this application because this product is ready for approval for use in adults and the 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)(3)(B) of the FDCA. These required studies are listed below.

2773-1 A PK-PD bridging simulation study must be conducted to determine the appropriate lacosamide monotherapy regimen for the treatment of partial-onset seizures in the pediatric population ≥ 1 month to < 17 years of age, and to support efficacy by extrapolation based on PK and efficacy data of lacosamide for adjunctive therapy for partial-onset seizures in pediatrics and adults, and efficacy for monotherapy for partial-onset seizures in adults. If the exposure-response relationship in younger children, e.g., less than 4 years old, is different from the older children and adult populations, this will be considered, and changes will be made accordingly.

Final Protocol Submission:	02/2018 (Statistical Analysis Plan)
Study Completion:	06/2018
Final Report Submission:	12/2018

2773-2 An open-label safety and tolerability study using lacosamide as monotherapy in pediatric patients ≥ 1 month to < 17 years of age.

Final Protocol Submission:	02/2019
Study Completion:	02/2023
Final Report Submission:	08/2023

2774-1 A safety study of replacement of oral dosing with intravenous dosing administered over 30 to 60 minutes in pediatric patients ≥ 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.

Final Protocol Submission:	07/2015
Study Completion:	08/2017
Final Report Submission:	01/2018

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.

Final Protocol Submission:	03/2019
Study Completion:	09/2020
Final Report Submission:	03/2021

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.

Final Protocol Submission:	03/2019
Study Completion:	09/2020
Final Report Submission:	03/2021

Please allow for adequate time for Agency review and comment on each of the protocols, and for agreement on the protocols, prior to the final protocol submission dates.

Submit the protocols to IND 057939 and IND 073809, with a cross-reference letter to this NDA.

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 these studies. 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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), 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 http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, MHA, Regulatory Project Manager, at (301) 796-4098.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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.