DOCUMENT INFORMATION PAGE

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	NDA 022253/S-042 (tablets) NDA 022254/S-033 (injection) NDA 022255/S-024 (oral solution)
Communication Type:	Correspondence
Communication Group:	sNDA Action
Communication Name:	Approval
Communication ID:	COR-SNDAACTION-05
Drafted by:	S.N. Parncutt 11/9/18;
Clearance History by:	AH 11/9/18
Finalized:	
Filename:	C:\Users\PARNCUTTS\Documents\EPILEPSY\NDA's\NDA 22-253 Vimpat Tab\S-042 PAS\Letters\sNDA Approval [Rx ONLY] (11-9-18).docx
Signatory Authority:	**For Efficacy Supplements or Labeling Supplements:** OND Division Director or Deputy Division Director. Person who is covering for the signatory authority can sign on their behalf (i.e., the signature block on the letter will not change) **For CMC Supplements with Labeling:** OPQ Division Director or Branch Chief
Use Statement:	Use to notify applicant of an approval action for a supplemental application that includes changes to the label(s) and/or labeling
Notes:	USE "sNDA Approval [OTC ONLY]" template for Over-the-Counter sNDA Approvals USE COR-SNDAACTION-06 FOR sNDA CMC APPROVALS USE COR-SNDAACTION-09 FOR sNDA TENTATIVE APPROVALS If supplement approval also fulfills a PMR/PMC, this letter will need to be double-coded as PMR-PMC Fulfilled. **Note:** Remember to check for acceptability of facility **prior to issuing approval letter**. **Labeling:** Before attaching labeling, ensure that the following items have been addressed (see *"Final Check of Labeling Format Before Attaching Documents to Approval Letter"* slide presentation on *LDT's intranet site* for details): 1) No annotations (e.g., tracked changes, comments, content in headers/footers); however, page numbers are allowed (see #5) 2) No line numbers 3) Assess number of columns in three sections of labeling (two columns for Highlights and Table of Contents, and one-column for Full Prescribing Information). If incorrect, ask applicant to address. 4) Correct/update dates in Highlights (e.g., Initial U.S. Approval, Recent Major Changes, and Revision Date)

5) If page numbers are included, first page of each labeling document must start with Page #1 (e.g. Prescribing Information, Patient Package Insert, Medication Guide, Instructions for Use)

Version: 10/31/2018

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022253/S-042
NDA 022254/S-033
NDA 022255/S-024

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Laila El-Asmar, Ph.D.
Associate Director, Regulatory Affairs
1950 Lake Park Drive
Building 2100
Smyrna, GA 30080

Dear Dr. El-Asmar:

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 & received on:
NDA 022253/S-042	Vimpat (lacosamide) tablets	May 11, 2018
NDA 022254/S-033	Vimpat (lacosamide) injection	
NDA 022255/S-024	Vimpat (lacosamide) oral solution	

These Prior Approval supplemental new drug applications provide for revisions to the Warnings and Precautions (Section 5.3—Cardiac Rhythm and Conduction Abnormalities), Dosage and Administration, Drug Interactions, Overdosage, and Patient Counseling Information sections of the Prescribing Information, as well as the Medication Guide, to reflect new information related to the risk for serious cardiac events (e.g., cardiac arrest, asystole, atrioventricular block, and ventricular arrhythmias). In addition, these Prior Approval supplemental new drug applications provide for revisions to Section 5.6 (Warnings and Precautions; Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS]/Multi-Organ Hypersensitivity) to reflect that DRESS has been reported in patients treated with Vimpat and to provide greater consistency with the language related to the risk for DRESS in other antiepileptic drug labels.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are 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 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 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 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).

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}

Alice Hughes, M.D.
Deputy Director for Safety
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

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.

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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.

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

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Litigation and bankruptcy checks for companies and debtors.

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