



NDA 022253/S-023  
NDA 022254/S-015  
NDA 022255/S-009

**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 Application (sNDA) dated April 6, 2012, received April 6, 2012, 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 acknowledge receipt of your amendments dated May 3, 2013; October 11, 2013; October 22, 2013; November 19, 2013; and December 9, 2013.

This “Changes Being Effected” supplemental new drug application provides for new unit dose packaging for use in hospitals and long-term care settings. The unit dose packaging configuration contains a carton with 6 blister cards and 10 unit dose tablets per card for a total of 60 unit dose tablets per carton. This unit dose packaging configuration will be available for the 50 mg, 100 mg, 150 mg, and 200 mg strength tablets. Included in this submission is the revised package insert containing the new unit dose configuration for each strength in the “How Supplied” section.

Also included in the package insert are revisions to the language in the “Highlights” and the “Dosage and Administration” section that were made for reasons dosage clarification and to comply with the FDA style. These revisions were recommended by the FDA and agreed upon by the Sponsor.

**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).

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on November 19, 2013 and December 9, 2013, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 022253/S-023; NDA 022254/S-015; NDA 022255/S-009.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## **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

NDA 022253/S-023  
NDA 022254/S-015  
NDA 022255/S-009  
Page 3

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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ERIC P BASTINGS  
01/16/2014