DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021035/S-093
NDA 021505/S-033
NDA 021872/S-017
NDA 022285/S-017

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Debra Hayes, RAC
Senior Manager, Regulatory Affairs
1950 Lake Park Dr.
Building 2100
Smyrna, GA 30080

Dear Ms. Hayes:

Please refer to your Supplemental New Drug Applications (sNDA):

Application	Product Name	Submitted on:	Received on:
NDA 021035/S-093	Keppra (levetiracetam) Tablets	September 30, 2013	October 1, 2013
NDA 021505/S-033	Keppra (levetiracetam) Oral Solution	September 30, 2013	October 1, 2013
NDA 021872/S-017	Keppra (levetiracetam) Tablets	September 30, 2013	October 1, 2013
NDA 022285/S-017	Keppra (levetiracetam) XR	September 30, 2013	October 1, 2013

These supplements, submitted as "Changes Being Effected" labeling supplements, provide for:

- Addition of "drug rash with eosinophilia and systemic symptoms (DRESS)" to Section 6.2—Adverse Reactions; Postmarketing Experience
- Revision of the Warnings and Precautions subsection pertaining to hematologic abnormalities to note that cases of agranulocytosis have been reported in the postmarketing setting
- Removal of references to the UCB Pregnancy Registry in Section 8.1—Use in Specific Populations; Pregnancy, Section 17—Patient Counseling Information, and the Medication Guide

We acknowledge receipt of your amendments dated March 21, 2014, July 2, 2014, and August 21, 2014.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. 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 package insert, 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 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).

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, contact Laurie Kelley, PA-C, Regulatory Project Manager, via telephone at (301) 796-5068 or via email at Laurie.Kelley@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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ALICE HUGHES
03/10/2015