DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021872/S-016

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

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 Application (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA Number	Supplement Number	Product Name	Submission Date	Receipt Date
021872	S-016	Keppra (levetiracetam) Injection	September 27, 2013	September 30, 2013
This "Prior Approval" supplemental new drug application proposes:				
Labeling changes to incorporate new pediatric safety data derived from previously submitted pediatric Postmarketing Requirement studies.				

We acknowledge receipt of your amendments dated:

November 12, 2013	January 28, 2014	February 10, 2014	February 24, 2014
February 28, 2014	April 7, 2014	July 10, 2014	August 20, 2014
September 3, 2014	October 29, 2014		

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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, 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.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated September 30, 2013, containing the final report for the following postmarketing requirement listed in the July 31, 2006, approval letter.

> 351-1 Deferred pediatric study under PREA for a pharmacokinetic and safety study in 30 pediatric patients ages four to 16 years

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

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our July 31, 2006, letter.

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 me, via telephone at (301) 796-5068 or via email at Laurie.Kelley@fda.hhs.gov.

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

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

/s/

ERIC P BASTINGS
10/30/2014