DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021035/S-094
NDA 021505/S-034
NDA 021872/S-018
NDA 022285/S-020

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-094	Keppra (levetiracetam) Tablets	June 17, 2014	June 18, 2014
NDA 021505/S-034	Keppra (levetiracetam) Oral Solution	June 17, 2014	June 18, 2014
NDA 021872/S-018	Keppra (levetiracetam) Tablets	June 17, 2014	June 18, 2014
NDA 022285/S-020	Keppra (levetiracetam) XR	June 17, 2014	June 18, 2014
These supplements, submitted as a "Changes Being Effected" propose:			
To update Section 6.2 Postmarketing Experience with a new adverse reaction: "hyponatremia"			

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

These "Changes Being Effected" supplemental new drug applications propose to update Section 6.2 Postmarketing Experience with a new adverse reaction "hyponatremia".

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).

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}

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
08/07/2014