



NDA 021035/S-091
NDA 021505/S-031
NDA 021872/S-015
NDA 022285/S-016 & S-019

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Kristen Piatak, RAC
Associate Director, Regulator Affairs
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Ms. Piatak:

Please refer to your Supplemental New Drug Applications (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
021035	S-091	Keppra (levetiracetam) Tablets 250 mg, 500 mg, 750 mg, 1000 mg	June 22, 2012	June 25, 2012
021505	S-031	Keppra (levetiracetam) Oral Solution 100 mg/mL	June 22, 2012	June 25, 2012
021872	S-015	Keppra (levetiracetam) Injection 500 mg/5 mL	June 22, 2012	June 25, 2012
022285	S-016	Keppra (levetiracetam) Extended Release Tablets 500 mg, 750 mg	June 22, 2012	June 25, 2012
These “Changes Being Effected” supplemental new drug applications propose:				
The addition of new adverse reactions “muscle weakness” and “panic attack” to the Adverse Reactions, Postmarketing Experience section of the labeling.				

We also acknowledge receipt of your amendments to each NDA, dated August 8, 2013.

Please also 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
022285	S-019	Keppra (levetiracetam) Extended Release Tablets 500 mg, 750 mg	February 17, 2014	February 19, 2014
This “Changes Being Effected” supplemental new drug application provides for:				
Agency requested changes to the once daily dosing language of the package insert as well as the immediate container labels.				

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.

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, container labeling), 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).

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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

- Package Inserts
- Container 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
03/07/2014