DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021035/S-089
NDA 021505/S-030
NDA 021872/S-012/S-013
NDA 022285/S-013/S-015

SUPPLEMENT APPROVAL

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

Dear Ms. Hayes:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Drug Product	Submitted on:	Received on:
NDA 021035/S-089	Keppra (levetiracetam) tablets	July 8, 2011	July 11, 2011
NDA 021505/S-030	Keppra (levetiracetam) oral solution	July 14, 2011	July 15, 2011
NDA 021872/S-012	Keppra (levetiracetam) injection	July 8, 2011	July 11, 2011
NDA 022285/S-013	Keppra (levetiracetam) XR tablets	July 8, 2011	July 11, 2011
These "Changes Being Effected" supplements provide for:			
Addition of adverse reactions choreoathetosis and dyskinesia in the Postmarketing Experience subsection of the labeling.			

Application	Drug Product	Submitted on:	Received on:	Amended on:
NDA 021872/S-013	Keppra (levetiracetam) injection	April 13, 2012	April 16, 2012	June 29, 2012
NDA 022285/S-015	Keppra (levetiracetam) XR tablet	April 13, 2012	April 16, 2012	June 29, 2012

The "Prior Approval" supplements provide for:

- Revision of the Carcinogenesis, Mutagenesis, Impairment of Fertility subsection to update information regarding a 2-year oral mouse carcinogenicity study, to be consistent with the Keppra tablet/oral solution approved labeling.
- Addition of information regarding seizure control during pregnancy and decreased levetiracetam drug levels to the WARNINGS AND PRECAUTIONS section and the Pregnancy subsection of labeling, to be consistent with the Keppra tablet/oral solution approved labeling.
- Addition of information regarding serious dermatological reactions to the WARNINGS AND PRECAUTIONS section of labeling, and to the Keppra-XR Medication Guide, to be consistent with the Keppra tablet/oral solution approved labeling.
- Other revisions to the information in the WARNING AND PRECAUTIONS section, to be consistent with the Keppra tablet/oral solution approved 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.

(b) (4)

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 applications, you are exempt from this requirement.

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 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/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. 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.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Fannie Choy, Regulatory Project Manager, by phone or email at (301) 796-2899 or fannie.choy@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Acting 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
07/25/2013