DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21872/S-021

SUPPLEMENT APPROVAL

UCB, Inc.
4600 East-West Highway, Suite 350
Bethesda, MD 20814

Attention: Susan Tegtmeyer, M.S.
Associate Director, Regulatory Affairs

Dear Ms. Tegtmeyer:

We have received your Supplemental New Drug Application (sNDA) submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for Keppra Injection (levetiracetam), 500 mg/5 mL (100 mg/mL).

The supplemental application makes the following changes to the Package Insert (underlined text added):

1. Delete Section 2.8 Compatibility and Stability.

2. Move the diluent information from Section 2.8 Compatibility and Stability to Section 2.6 Preparation and Administration Instructions.

3. Section 2.6: Delete the statement regarding Keppra Injection being stable for at least 24 hours when mixed with diluents and change it to "KEPPRA injection may be mixed with the following diluents and antiepileptic drugs and may be stored in polyvinyl chloride (PVC) bags. The diluted solution should not be stored for more than 4 hours at controlled room temperature [15-30ºC (59-86ºF)]." List of diluents follows. Additional Statement: There are no data to support the physical compatibility of KEPPRA injection with antiepileptic drugs that are not listed above.

4. Update Section Highlights contact information for reporting Suspected Adverse Reactions by changing the phone number from 866-822-0068 to (844) 599-CARE (2273).

APPROVAL & LABELING

We have completed our review of this supplemental application. The application 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, 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 Q's and A's" 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 these NDAs, 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 these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, 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, call Cathy Michaloski, Sr. Regulatory Project Manager, at (301) 796-1123.

Sincerely,
{See appended electronic signature page}

Billy Dunn, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
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/

WILLIAM H Dunn
04/06/2016