DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22285/S-022

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 XR (levetiracetam) 500 and 750 mg tablets.

The supplemental application includes the following changes to the Package Insert and Medication Guide (underlined text added):

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

2. Update Section 17.0 Patient Counseling Information – Dosing and Administration: addition of statement: Inform patients that they should not be concerned if they occasionally notice something that looks like swollen pieces of the original tablet in their stool.

3. MEDICATION GUIDE
Update Medication Guide to include the following language under "How should I take Keppra?" The inactive part of Keppra XR tablets may not dissolve after all the medicine has been released in your body. You may sometimes notice something in your bowel movement that looks like swollen pieces of the original tablet. This is normal.

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