DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205836/S-001
NDA 205837/S-001
NDA 205838/S-001

SUPPLEMENT APPROVAL

UCB, Inc.
1950 Lake Park Drive
Smyrna, GA 30080

Attention: Kristen Piatak, RAC
Associate Director, Regulatory Affairs

Dear Ms. Piatak:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received May 12, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for brivaracetam (Briviact), tablets, injection, and oral solution.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the "CV" symbol as appropriate to the prescribing information and the Medication Guide. Specifically, the application provides for the following additions (with added text underlined):

Prescribing Information:
- "CV" was added to the Highlights Section after "Briviact (brivaracetam) for each formulation.
- The following statement (underlined) was added to **Section 9.1 Controlled Substance**: "BRIVIACT contains brivaracetam and is listed as a Schedule V controlled substance.

Medication Guide:
- "CV" after "BRIVIACT" at the top of the Medication Guide; and
- "CV" added to the following statement: "BRIVIACT is a federally controlled substance (CV) because it can be abused or cause dependence."

Carton and Container Labels:
All components have been edited to reflect the controlled substance symbol, "CV".

APPROVAL & LABELING

We have completed our review of this supplemental application. 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 and 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 include 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).

PROMOTIONAL MATERIALS

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, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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 Cathleen Michaloski, Sr. Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Eric P. Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Carton and 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
06/03/2016