



NDA 205836/S-009
NDA 205837/S-007
NDA 205838/S-006

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT**

UCB, Inc
Attention: Sathya Ganesan PhD, RAC
Regulatory Science Lead
4000 Paramount Parkway, Suite 200
Morrisville, NC, 27560

Dear Dr. Ganesan:

Please refer to your supplemental new drug applications and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number/Supplement Number	Drug Product	Date of Submission	Date of Receipt	Date of Amendment
NDA 205836/S-009	Briviact (brivaracetam) tablets	October 26, 2020	October 28, 2020	February 27, 2021
NDA 205837/S-007	Briviact (brivaracetam) injection	October 26, 2020	October 27, 2020	February 26, 2021
NDA 205838/S-006	Briviact (brivaracetam) oral solution	October 26, 2020	October 27, 2020	February 26, 2021

These Prior Approval supplemental new drug applications propose the following changes for Briviact (brivaracetam): expanding the patient population to include pediatric patients ages 1 month to less than 4 years for brivaracetam tablets and oral solution, and expanding the patient population to include pediatric patients ages 1 month to less than 16 years for brivaracetam injection.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 *SPL Standard for Content of Labeling Technical Qs and As*.²

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 (which includes new salts and new fixed combinations), 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

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submissions dated October 26, 2020, and February 26, 2021, containing the final report for the following postmarketing requirement listed in the February 18, 2016, approval letter:

3042-2 A pharmacokinetic and safety analysis in children from 1 month to less than 16 years of age to determine whether the bioavailability of the intravenous and oral formulations is similar and to determine an acceptable safety margin of the intravenous formulation when administered at doses that are found acceptable for oral administration. The study should include routine safety monitoring including careful cardiac monitoring before, during, and after infusion. Subjects should be balanced among age cohorts.

Final Protocol Submission:	08/2016
Study/Trial Completion:	01/2020
Final Report Submission:	06/2020

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the February 18, 2016, approval letter and the May 10, 2018, postapproval postmarketing requirement letter, that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

You must submit final promotional materials and Prescribing Information, 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 FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

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 Tina Chhabra, Regulatory Project Manager via email at Tina.Chhabra@fda.hhs.gov or via telephone at 301-837-7205.

Sincerely,

{See appended electronic signature page}

Nick Kozauer, MD
Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NICHOLAS A KOZAUER
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