NDA 212839/S-009
NDA 212839/S-010

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

SK Life Science, Inc
Attention: Jeremy Rybicki
Director, Regulatory Affairs
461 From Road, 5th Floor
Paramus, NJ 07652

Dear Jeremy Rybicki:

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

NDA/Supplement number	Product name	Date of Submission/Receipt
NDA 212839/S-009	Xcopri (cenobamate)	October 6, 2023
NDA 212839/S-010	Xcopri (cenobamate)	October 6, 2023

These Prior Approval sNDAs proposed and provide for:

- NDA 212839/S-009: Updates to the Use in Specific Populations/Hepatic Impairment (8.7) and Clinical Pharmacology/Pharmacokinetics (12.3) sections of the prescribing information (PI) regarding use in patients with hepatic impairment.

- NDA 212839/S-010: Updates to the Dosage and Administration/Important Administration Instructions (2.3) section of the PI regarding crushing the tablet and administration via a nasogastric tube. Corresponding edits were also made to the Medication Guide.

In addition, these sNDAs provide for:

- An update to the Description (11) section of the PI regarding the solubility of cenobamate.

- Updates to the How Supplied/Storage and Handling (16.1) section of the PI to add that Xcopri is supplied in a 30-count bottle for the 25 mg strength and a 14-day titration blister pack.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- Correction of the cross-reference number to the Dosage and Administration section from 2.3 to 2.2 in the Hepatic Impairment (8.7) and Pharmacokinetics (12.3) subsections of the PI

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 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 *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 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 Microsoft Word format, that includes the changes approved in these supplemental applications, 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).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated October 6, 2023, containing the final report for the following postmarketing requirement listed in the November 21, 2019, approval letter.

[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.

3712-12 Conduct a clinical pharmacokinetic trial to determine an appropriate dose of Xcopri (cenobamate) to minimize toxicity in patients with severe hepatic impairment. Design and conduct the trial in accordance with the FDA Guidance for Industry entitled, "Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling".

Draft Protocol Submission: 06/2020
Final Protocol Submission: 09/2020
Trial Completion: 09/2021
Final Report Submission: 03/2022

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

We remind you that there are postmarketing requirements listed in the November 21, 2019, approval 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]

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]

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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, Senior Regulatory Health Project Manager, via email at Tina.Chhabra@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Paul R. Lee, MD, PhD
Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

PAUL R LEE
04/05/2024 03:55:19 PM