



NDA 201635/S-025

**SUPPLEMENT APPROVAL**

Supernus Pharmaceuticals, Inc.  
Attention: Tami Martin, RN, Esq  
Sr. Vice President, Regulatory Affairs  
9715 Key West Avenue  
Rockville, MD 20850

Dear Ms. Martin:

Please refer to your supplemental new drug application (sNDA) dated and received May 18, 2020, and your amendment, submitted October 8, 2020 under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trokendi XR (topiramate extended-release) capsule.

This Changes Being Effected sNDA provides for the addition of nephrocalcinosis as a new adverse reaction in the Postmarketing Experience subsection in Section 6 of the Prescribing Information. An amendment dated October 8, 2020, was subsequently submitted after an additional revision, the addition of serious skin reactions (Section 5.9), was approved for the listed drug in June 2020.

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is 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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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*.<sup>2</sup>

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).

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

<sup>2</sup> 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>.

If you have any questions, call Alina Salvatore, Regulatory Project Manager, at 240-402-0379.

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

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**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.**  
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/s/  
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NICHOLAS A KOZAUER  
11/18/2020 11:40:03 AM