DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201635

TENTATIVE APPROVAL

Supernus Pharmaceuticals, Inc.
Attention: Tami T. Martin, RN, Esq.
Vice President, Regulatory Affairs
1550 East Gude Drive
Rockville, MD 20850

Dear Ms. Martin:

Please refer to your New Drug Application (NDA) dated January 13, 2011, received January 14, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Trokendi XR (topiramate) extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

We acknowledge receipt of your additional amendments dated:

July 26, 2012	January 24, 2013	March 25, 2013 (2)	May 29, 2013
October 31, 2012	February 27, 2013	March 28, 2013	June 4, 2013
November 26, 2012	March 18, 2013 (2)	April 15, 2013	June 5, 2013
December 4, 2012			

The December 4, 2012, submission constituted a complete response to our June 25, 2012, Tentative Approval letter.

This NDA provides for a new extended-release dosage form (i.e., capsule) of topiramate for:

- initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures
- adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures
- adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert and Medication Guide) and submitted labeling (text carton and immediate container labels submitted June 5, 2013). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug upon which your application relies is subject to a period of exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired. A tentative approval, and not an approval, is necessary because of the existence of protected information included in the present Topamax labeling that provides safety information in patients 1 to 24 months of age, and is considered necessary for safe use.

To obtain final approval of this application, submit an amendment two or six months prior to either (1) the expiration of the exclusivity protection or (2) the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. The amendment should also include all proposed labeling (text for the package insert, Medication Guide, and carton and container labels). In addition, the amendment should identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and Risk Evaluation and Mitigation Strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

If you have any questions, contact Taura Holmes, PharmD, Regulatory Project Manager, via telephone at (301) 796-1932 or via email at Taura.Holmes@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling –
(Prescribing Information and Medication Guide)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
06/07/2013