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, 200 mg.

We acknowledge receipt of your additional amendments dated:

February 1, 2011	October 14, 2011	February 2, 2012	May 2, 2012
February 23, 2011	December 7, 2011	February 14, 2012	May 15, 2012
March 25, 2011	December 22, 2011	February 23, 2012	May 17, 2012
April 13, 2011	January 12, 2012	March 22, 2012	June 25, 2012
June 1, 2011	January 16, 2012	April 19, 2012	
August 30, 2011	January 18, 2012	April 26, 2012	

Your August 30, 2011, submission constituted a complete response to our March 14, 2011, Refusal-To-File letter.

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

- 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, Medication Guide, and immediate container labels). 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 no sooner than 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. You should determine the timing of your amendment by referring to the resubmissions classifications and the associated FDA review timelines described in the Guidance for Industry: Classifying Resubmissions in Response to Actions Letters (http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093430.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=resubmissions%20guidance&utm_content=3). If you believe that there are grounds for issuing the final approval letters before the expiration of exclusivity protection, you should amend your application accordingly.

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. In addition to a safety update, the amendment should also 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, call Jacqueline H. Ware, PharmD, Senior Regulatory Project Manager, at (301) 796-1160.

Sincerely yours,

{See appended electronic signature page}

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

ENCLOSURE:
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
06/25/2012