DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201-635/S-011

TENTATIVE APPROVAL

Supernus Pharmaceuticals, Inc.
Attention: Tami Martin, R.N., Esq.
1550 East Gude Drive
Rockville, MD 20850

Dear Ms. Martin:

Please refer to your supplemental New Drug Application (sNDA) dated and received August 12, 2015, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Trokendi XR (topiramate) extended release capsules.

We acknowledge receipt of your amendment dated June 21, 2016, which constituted a complete response to our June 10, 2016, action letter.

This supplemental new drug application provides for the use of Trokendi XR (topiramate) for the prophylaxis of migraine headache in adults.

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**)**. 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 product upon which you based your application 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.

Two or six months prior to the expiration of the exclusivity protection, as appropriate, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. Any change in the conditions outlined in this application requires our review before final approval and the goal date for our review will be set accordingly. Your amendment should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Before we issue a final approval letter, this application is not deemed approved. If you believe that there are grounds for issuing the final approval letter before the expiration of the exclusivity protection, you should amend your application accordingly.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, call Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ERIC P BASTINGS
08/18/2016