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November 08, 2019

William Dunn, M.D., Director
Division of Neurology Products (HFD-120)
Center for Drug Evaluation and Research
Office of New Drugs
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

NDA #:	**201635**
Sponsor:	**Supernus Pharmaceuticals, Inc.**
Product:	**Trokendi XR, Topiramate Extended-Release Capsules**
Sequence #:	**0149**
Submission Type:	**PMR 2080-3 Deferral Extension Requested**

Dear Dr. Dunn:

Reference is made to NDA 201635 for Trokendi XR®, topiramate extended-release capsules.

Supernus Pharmaceutical, Inc. ("Supernus") is in receipt of your October 2, 2019 PREA Non-compliance letter. This submission requests a deferral extension of this pediatric commitment for which Supernus is responsible under NDA 201635.

Supernus has been diligently working on a (b) (4) formulation to address usage issues for children and infants that cannot swallow an intact capsule, as required for use of Trokendi XR. A (b) (4) formulation was considered best to cover all age groups for which Supernus holds postmarketing commitments. Efforts to create a (b) (4) formulation, to date, have been unsuccessful. Most recently, Supernus Contracted (b) (4) to develop age-appropriate formulations based on (b) (4) The resulting (b) (4) of the products showed that none were suitable for an extended-release formulation (b) (4) Additional formulation work needs to be undertaken to develop extended-release (b) (4) formulations. A copy of this development report, was in the Annual Report to NDA 201635(Seq 0148 Module 1.9.6) that was submitted on October 30, 2019.We are still looking at trying to create a (b) (4) formulation with alternate vendors. Based on this, we are requesting another deferral of this PMR 2080-3 requirement.

As noted, the lower age groups represent some challenges as to (b) (4) we would like to utilize to create the desired formulations. Supernus would like come in to meet with the Agency for a Type C meeting to discuss efforts to date, challenges, and plans moving forward. We intend to submit this Type C meeting request under a separate submission.

We hope that you find this submission responsive to the non-compliance letter and also that you will find our plans for a future meeting acceptable.

This official submission is being provided in electronic Common Technical Document (eCTD) format. The entire content of this submission is provided by a third party vendor via the E-submissions gateway on behalf of Supernus Pharmaceuticals, Inc. This application has been verified and confirmed to be virus-free.

Please contact the undersigned for any communications concerning this submission.

Sincerely,

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