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November 12, 2015

William Dunn, M.D., Acting 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®, SPN-538, Topiramate Extended-Release Capsules**
Sequence #:	**S0083**
Submission Type:	**Response to PREA Non-compliance Letter Revised Pediatric Plan**

Dear Dr. Dunn:

This submission pertains to NDA 201635 which received an NDA Approval on August 16, 2013.

Response to PREA Non-Compliance Letter

Supernus is in receipt of your September 29, 2015 PREA Non-compliance letter. This submission requests an extended deferral of pediatric commitments for which Supernus is responsible under NDA 201635.

Revised Pediatric Plan

Please see the revised Pediatric Plan (Module 1.9.6) for details on work conducted to date, and plans for continued activities to develop an extended-release formulation of topiramate bioequivalent to Trokendi XR, and suitable for use in children ages 1 month and older. In general, we believe now that we need to (b) (4)

(b) (4)

We hope that you find this submission responsive to the non-compliance letter, and also that you will find this revised Pediatric Plan acceptable.

If helpful, Supernus is willing to come meet with the agency on this topic, regarding efforts to date, challenges, and plans moving forward.

This correspondence is submitted as part of an electronic Common Technical Document (eCTD) and is organized in accordance with the Agency's Guidance for Industry, "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using eCTD Specifications (June 2008)." See attached Electronic Submission Specifications.

This submission contains materials for one module:

Module 1: Administrative Information including

Cover letter
Form FDA 356h
1.9.6 Other correspondence (revised Pediatric Plan)
1.9.6 PREA Non-compliance letter (dated 29September 2015)

Please contact Tami Martin, Vice President, Regulatory Affairs at 301-838-2607 (additional contact information below) with any questions or comments about this submission.

Sincerely,

Tami Martin

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