

Supernus Pharmaceuticals, Inc.

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March 10, 2017

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: 202810
Sponsor: Supernus Pharmaceuticals, Inc. ("Supernus")
Product: Oxtellar XR®, SPN-8040, Oxcarbazepine Extended-Release Tablets
Submission Type: REQUEST FOR PEDIATRIC DEFERRAL EXTENSION
Sequence #: 0064

Dear Dr. Dunn:

This submission pertains to NDA 202810, Oxtellar XR® (oxcarbazepine extended-release tablets), which received full approval on October 19, 2012. This submission contains a request for a further deferral of pediatric commitments for this NDA, in response to a PREA Noncompliance Letter dated January 12, 2017.

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)."

This submission contains materials for one module:

Module 1: Administrative Information, including:

- Cover letter
- Form FDA 356h
- Module 1.4.2 Statement of Right of Reference
- Module 1.9.2 Request for Deferral of Pediatric Studies

The entire content of this submission is provided by a third party vendor (b) (4), a division of (b) (4) via the E-submissions gateway on behalf of Supernus Pharmaceuticals, Inc. This application has been verified and confirmed to be virus-free.

Supernus Pharmaceutical, Inc. considers the material and data contained in this Sequence to be confidential and not to be publically disclosed.

Please contact Tami Martin, Sr. Vice President, Regulatory Affairs with any questions or comments about this submission.

Sincerely,

A handwritten signature in blue ink that reads "Tami Martin". The signature is written in a cursive style.

Tami Martin, RN, Esq.
Sr. Vice President, Regulatory Affairs
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