CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

202810Orig1s000

Trade Name:	Oxtellar XR extended-release tablets 150mg, 300mg, and 600mg.
Generic Name:	oxcarbazepine
Sponsor:	Supernus Pharmaceuticals, Inc.
Approval Date:	October 19, 2012
Indications:	For use as recommended in the enclosed agreed-upon labeling text.

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202810Orig1s000

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202810

NDA APPROVAL

Supernus Pharmaceuticals, Inc.
Attention: Tami 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 December 19, 2011, received December 19, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Oxtellar XR (oxcarbazepine) extended-release tablets 150mg, 300mg, and 600mg.

We acknowledge receipt of your amendments dated December 21, 2011; February 8, 2012; February 24, 2012; March 19, 2012; April 10, 2012; April 25, 2012; May 21, 2012 (2); May 25, 2012; June 15, 2012; June 21, 2012; June 27, 2012; July 3, 2012; July 12, 2012; July 24, 2012; July 26, 2012; August 6, 2012; August 9, 2012; August 13, 2012; August 22, 2012; August 29, 2012; August 30, 2012, September 6, 2012; September 10, 2012; and October 17, 2012.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on October 17, 2012, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 202810**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

ADVISORY COMMITTEE

Your application for Oxtellar XR (oxcarbazepine) extended-release tablets was not referred to an FDA advisory committee because Oxtellar XR is an extended release form of an API (oxcarbazepine) with a well characterized safety and efficacy profile. In addition, the application did not raise significant safety or efficacy issues.

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages birth to one month of age because necessary studies are impossible or highly impracticable. Studying the effects of treatment in neonates with seizures is not feasible due to difficulties in characterizing the type of seizures in neonates and accurately quantifying the frequency of such seizures. Neonatal seizures also have different pathophysiology than seizures that occur in older children and respond differently to antiepileptic drugs.

We are deferring submission of your pediatric studies for ages one month to less than 6 years of age for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. The required studies are listed below.

1938-1 Deferred pediatric trial under PREA: A prospective, randomized, controlled, double-blind, efficacy/safety study of oxcarbazepine ER for the adjunctive treatment of partial onset seizures in children ages one month to < 2 years. The primary efficacy endpoint during the controlled phase will examine seizure frequency based upon Video/EEG data.

Final Protocol Submission:	March 2017
Trial Completion:	March 2021
Final Report Submission:	September 2021

1938-2 Deferred pediatric trial under PREA: A prospective, randomized, controlled, double-blind, efficacy/safety study of oxcarbazepine ER for the adjunctive treatment of partial onset seizures in children ages 2 to <6 years. The primary efficacy endpoint during the controlled phase will examine seizure frequency based upon diary data.

Final Protocol Submission:	March 2017
Trial Completion:	March 2021
Final Report Submission:	September 2021

1938-3 A clinical trial to examine pharmacokinetics and tolerability in children ages 6 months to 4 years using an age appropriate extended release oxcarbazepine formulation.

Final Protocol Submission:	June 2015
Trial Completion:	June 2016
Final Report Submission:	December 2016

1938-4 A clinical trial to examine pharmacokinetics and tolerability in children, ages 1 month to 6 months, using an age appropriate extended release oxcarbazepine formulation.

Final Protocol Submission:	June 2015
Trial Completion:	June 2016
Final Report Submission:	December 2016

Submit the protocols to your IND 077417, with a cross-reference letter to this NDA.

Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

We note that you have fulfilled the pediatric study requirement for ages 6 to 17 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Stephanie N. Parncutt, M.H.A., Regulatory Health Project Manager, at (301) 796-4098.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

RUSSELL G KATZ
10/19/2012