



NDA 202810/S-014

SUPPLEMENT APPROVAL

Supernus Pharmaceuticals, Inc.
Attention: Tami Martin, RN, Esq.
Senior Vice President, Regulatory Affairs
9715 Key West Avenue
Rockville, MD 20850

Dear Ms. Martin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 14, 2023, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Oxtellar XR (oxcarbazepine) extended release tablet.

This “Changes Being Effected” supplemental new drug application provides for the addition of 7-count bottle (container) labels for the 150 mg, 300 mg, and 600 mg strength Oxtellar XR Tablets.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on June 20, 2023, 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 *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 202810/S-014.**” Approval of this submission by FDA is not required before the labeling is used.

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, please contact Erica Keafer, Regulatory Business Process Manager, at erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha

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