NDA 211964/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

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

Dear Ms. Martin:

Please refer to your supplemental new drug application (sNDA) dated June 29, 2021, received June 29, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Qelbree (viloxazine extended-release capsules).

This Prior Approval supplemental new drug application proposes the addition of safety and efficacy data for the use of Qelbree (viloxazine extended-release capsules) for the treatment of attention deficit hyperactivity disorder (ADHD) in adults. Qelbree is now indicated for the treatment of ADHD in adults and pediatric patients 6 years and older.

APPROVAL & LABELING

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

We note that your April 28, 2022, submission includes final printed labeling (FPL) for your Prescribing Information and Medication Guide. We have not reviewed this FPL. You are responsible for ensuring that the wording in this FPL is identical to that of the approved content of labeling in the structured product labeling (SPL) format

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

We acknowledge your April 7, 2022; April 20, 2022; April 21, 2022; and April 26, 2022, submissions containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA; 21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

We are waiving the pediatric studies requirement for 0 to less than 4 years of age because necessary studies are impossible or highly impracticable. Although pediatric patients younger than 4 years of age can exhibit ADHD-like behaviors, diagnosis and treatment recommendations for that age group have not been codified in recognized guidelines such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Most currently accepted measures for diagnosis and efficacy of treatment of ADHD in older age groups have not been validated for children younger than 4 years of age.

In our NDA 211964 approval letter of April 2, 2021, we deferred submission of your pediatric studies for patients 4 to younger than 6 years of age for this application. We remind you of these required studies below.

3942-1 Conduct an adequately powered, double-blind, placebo-controlled efficacy and safety study of viloxazine extended-release capsules (viloxazine ER) in male and female patients ages 4 to < 6 years with attention deficit hyperactivity disorder.

Final Protocol Submission:	06/2019
Study Completion:	03/2022
Final Report Submission:	09/2022

3942-2 Conduct a long-term (6-month), open-label safety extension study to evaluate the safety and tolerability of viloxazine extended-release capsules (viloxazine ER) as monotherapy for attention deficit hyperactivity disorder in male and female patients ages 4 to < 6 years.

Final Protocol Submission:	06/2019
Study Completion:	09/2022
Final Report Submission:	03/2023

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated June 29, 2021, containing the final study report for the following postmarketing requirement listed in the April 2, 2021, approval letter.

3942-5 Conduct a study to evaluate the pharmacokinetics of viloxazine extended-release capsules (viloxazine) in patients with hepatic impairment.

Final Protocol Submission:	06/2021
Study Completion:	09/2021
Final Report Submission:	06/2022

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the April 2, 2021, approval letter that remain open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and instructions for completing the form can be found at FDA.gov.[5]

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 CAPT Kofi Ansah, PharmD, RAC, Senior Regulatory Project Manager, at 301-796-4158 or email: Kofi.Ansah@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Bernard Fischer, MD
Deputy Director
Division of Psychiatry
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and Research

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

BERNARD A FISCHER
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