DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Terri Valentine, MS, RAC-US
Associate Director, Regulatory Affairs
Supernus Pharmaceuticals, Inc.
9715 Key West Avenue
Rockville, MD 20850

RE: NDA 211964
QELBREE® (viloxazine extended-release capsules), for oral use
MA 497

Dear Terri Valentine:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer broadcast advertisement (TV ad), titled "Flying Colors" (QBE.2023-0056), for QELBREE® (viloxazine extended-release capsules), for oral use (Qelbree), submitted by Supernus Pharmaceuticals, Inc. (Supernus) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Qelbree and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad begins with the protagonists showing obvious symptoms of attention deficit hyperactivity disorder (ADHD). The man is in the middle of several tasks in the kitchen, none of which are completed, and the woman has a disorganized desk with several sticky note reminders scattered around. After Qelbree is introduced, neither protagonist shows symptoms of ADHD. The man makes lunch for his daughter, finishes the laundry, and works at a tidy desk. The woman completes her work at an organized and clean desk, and she is attentive and focused throughout the workday. These images are presented with the audio claim, "To do lists…more like to done lists!" These presentations misleadingly suggest that Qelbree provides a greater magnitude of benefit in the treatment of ADHD than has been demonstrated. According to the CLINICAL STUDIES section of the FDA-approved prescribing information (PI), the primary endpoint of the adult clinical study was the change from baseline to the end of study on the total score on the ADHD Investigator Symptom Rating Scale (AISRS).[1] The mean AISRS score at baseline was 38.5 in the treatment group and 37.6 in the placebo group. Table 5 in the PI shows that the change in AISRS total score from baseline to the end of the study was -15.5 for the Qelbree-treated group and -11.7 for the placebo group. The magnitude of improvement in AISRS scores in the clinical study does not correlate with the complete resolution of symptoms portrayed in the TV ad. FDA acknowledges that the TV ad includes the voiceover, "[Qelbree] helps make symptoms manageable," and the SUPER, "Individual results may vary." However, these statements do

[1] The AISRS is an 18-item scale corresponding to 18 symptoms of ADHD. Higher AISRS scores reflect more severe symptoms.

not mitigate the misleading impression that adult patients can expect a complete resolution of ADHD symptoms when taking Qelbree.

The TV ad is misleading because frequent scene changes during the presentation of the major statement interfere with comprehension of the major statement. Additionally, the presentation of the serious risks associated with Qelbree juxtaposed with happy, smiling protagonists minimizes the risks of the drug.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Qelbree and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Supernus take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above). Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Qelbree that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Qelbree.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 497 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response

submission should be coded as an Amendment to eCTD Sequence 1486 under NDA 211964. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

George Tidmarsh, M.D., Ph.D.
Director
Center for Drug Evaluation and Research

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/

CARTER M BEACH
09/09/2025 05:16:10 PM
On behalf of George Tidmarsh, M.D., Ph.D