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 "Turn the Tables" (QBE.2021-0148), 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 a series of three frames of introduction for each of the three protagonists. The three frames start with the protagonist showing obvious symptoms of attention deficit hyperactivity disorder (ADHD). A young boy is hyperactive at dinner, an older boy is not paying attention in class, and a young girl is inattentive and disengaged at a bowling alley. After Qelbree is introduced in each series of frames, the protagonist's behavior changes. The young boy is engaging with his family at dinner and sitting calmly, the older boy is paying attention in class, and the young girl is focused on and engaged in a game of table tennis. For the rest of the TV ad, none of the protagonists show symptoms of ADHD. 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 three pediatric clinical studies was the change from baseline to the end of study on the total score on the ADHD Rating Scale (ADHD-RS-5).[1] The mean ADHD-RS-5 score in all treatment and placebo groups ranged from 39.4 to 45 at baseline. Table 4 in the PI shows that the change in ADHD-RS-5 total score from baseline to the end of the study ranged from -16.0 to -17.7 for the Qelbree-treated groups and -10.9 to -11.7 for the placebo groups. The magnitude of improvement in ADHD-RS-5 scores in the clinical studies does not correlate with the complete resolution of symptoms portrayed in the TV ad. FDA acknowledges that the TV ad includes the audio claim, "Qelbree helps make ADHD symptoms manageable," and the

[1] The ADHD-RS-5 is an 18-question scale that assesses hyperactivity, impulsivity, and inattentive symptoms. Higher ADHD-RS-5 scores reflect more severe symptoms.

SUPER, “Individual results may vary.” However, these statements do not mitigate the misleading impression that pediatric 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 05:15:57 PM
On behalf of George Tidmarsh, M.D., Ph.D