

CLINICAL REVIEW

Application Type	Class I Resubmission
Application Number(s)	211964
Submit Date(s)	February 3, 2021
Received Date(s)	February 3, 2021
PDUFA Goal Date	April 3, 2021
Division/Office	Division of Psychiatry/Office of Neuroscience
Reviewer Name(s)	Martine Solages, MD
Team Lead Name	Bernard Fischer, MD
Review Completion Date	March 10, 2021
Established/Proper Name	Viloxazine Extended Release (ER)
(Proposed) Trade Name	Quelbree
Applicant	Supernus Pharmaceuticals, Inc.
Dosage Form(s)	Extended-release capsule
Dosing Regimen(s)	Patients ages 6 to 11 years: 100 mg to 400 mg once daily Patients ages 12 to 17 years: 200 mg to 400 mg once daily
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s)	Treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age

On November 8, 2019, the Applicant submitted a 505(b)(1) new drug application (NDA) for viloxazine ER for the treatment of ADHD in children and adolescents ages 6 to 17 years. A Complete Response (CR) letter was issued on November 6, 2020, because of manufacturing facility deficiencies. The Applicant completed a CR resubmission on February 3, 2021, and has resolved the deficiencies that precluded approval of the application during the initial cycle.

The Agency and the Applicant did not reach full agreement on labeling prior to the CR action. Labeling negotiations therefore resumed after resubmission of the application. The most notable unresolved labeling issues pertained to the description of viloxazine's mechanism of action and effects on weight and suicidal ideation.

During the initial review cycle, the Applicant disagreed with the Agency on the description of viloxazine's mechanism of action and advocated for (b) (4). In a Type A meeting following the issuance of the CR letter, the Applicant proposed including language (b) (4)

(b) (4). The Agency noted (b) (4) the Applicant's proposed language would not be included in labeling. The Applicant submitted draft labeling with the CR resubmission that indicated acceptance of the Agency's position.

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/s/

MARTINE M SOLAGES
03/23/2021 08:20:37 AM

BERNARD A FISCHER
03/23/2021 09:05:29 AM
Supervisory Physician