

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

217684Orig1s000

CLINICAL PHARMACOLOGY
REVIEW(S)

Office of Clinical Pharmacology Memo

NDA Number	217684
Associated IND	157997
Regulatory Pathway	505(b)(2)
Link to EDR	\\CDSESUB1\evsprod\NDA217684\0003
Submission Date(s)	August 17, 2023
Brand Name	VIGAFYDE
Generic Name	Vigabatrin Oral Solution
Formulation and Strength	Oral solution 100 mg/mL
Route of Administration	Oral
Proposed Indication	Monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
Applicant	Pyros Pharmaceuticals, Inc.
OCP Review Team	Ramakrishna Samala, Ph.D. Gottipati Gopichand, Ph.D.

Executive Summary

The applicant, Pyros Pharmaceuticals, Inc., is seeking approval for Vigafyde™ (vigabatrin) oral solution under 505(b)(2) regulatory pathway as monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

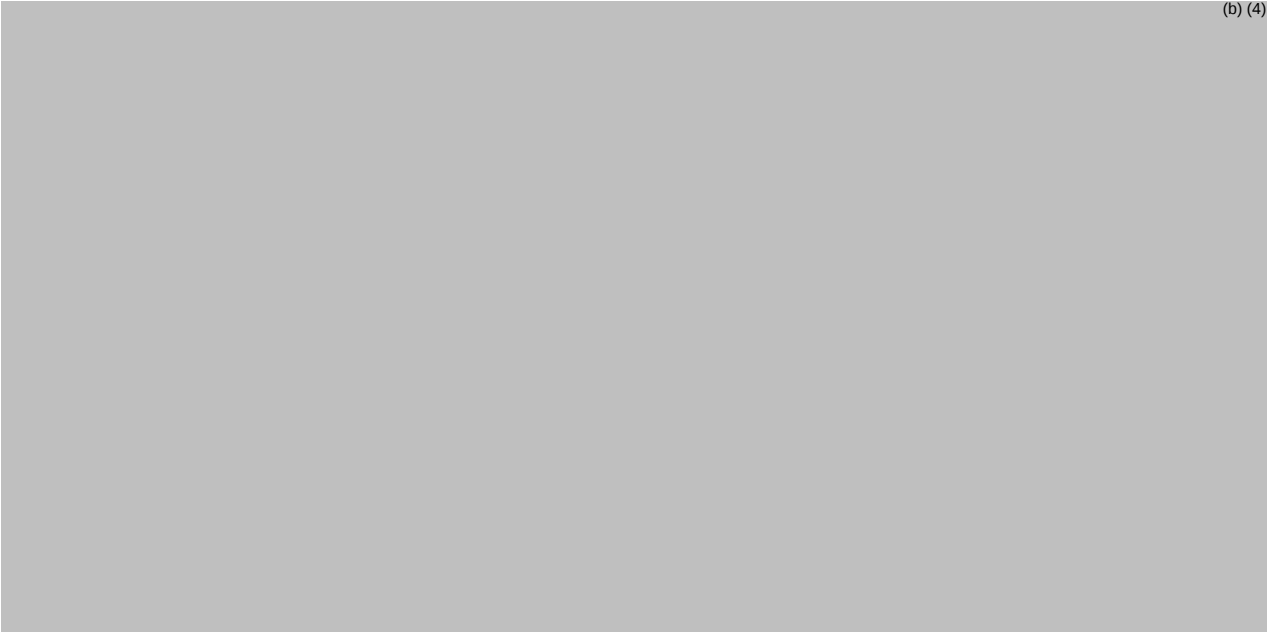
Vigafyde™ is a ready-to-use peppermint flavored vigabatrin 100 mg/mL solution. The proposed dosage regimen is same as the listed drug, Sabril® (NDA 022006, powder for oral solution approved by the FDA on 21-August-2009): initiate at a daily dose of 50 mg/kg (25 mg/kg twice daily); increase total daily dose every 3 days, in increments of 25 mg/kg/day to 50 mg/kg/day, up to a maximum daily dose of 150 mg/kg (75 mg/kg twice daily).

The applicant did not conduct any clinical pharmacology studies in the current NDA application. They submitted a request for biowaiver request, along with supporting justification. The Office of Clinical Pharmacology (OCP) review team defers to Biopharmaceutics team for biowaiver determination to support demonstration of an adequate scientific bridge to the listed drug.

The primary focus of this review is to justify the labeling revisions in relevant sections to provide appropriate instructions for safe use in intended population.

Summary of Labeling Revisions

(b) (4)



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/

RAMAKRISHNA SAMALA
05/23/2024 03:23:58 PM

GOPICHAND GOTTIPATI
05/23/2024 03:25:17 PM