CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

218879Orig1s000

Trade Name:	SUBVENITE
Generic or Proper Name:	Lamotrigine
Sponsor:	OWP Pharmaceuticals Inc.
Approval Date:	September 16, 2025
Indication:	Epilepsy—adjunctive therapy in patients aged 2 years and older: • partial-onset seizures • primary generalized tonic-clonic (PGTC) seizures • generalized seizures of Lennox-Gastaut syndrome. Epilepsy—monotherapy in patients aged 16 years and older: Conversion to monotherapy in patients with partial-onset seizures receiving treatment with carbamazepine, phenytoin, phenobarbital or valproate as the single antiepileptic drug. Bipolar disorder: Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy.

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APPROVAL LETTER

NDA 218879

NDA APPROVAL

OWP Pharmaceuticals, Inc.
Attention: Paul Sudhakar
Director of Scientific Affairs
8827 Long St.
Lenexa, KS 66215

Dear Paul Sudhakar:

Please refer to your new drug application (NDA) dated March 1, 2024, and received March 4, 2024, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Subvenite (lamotrigine) oral suspension.

We acknowledge receipt of your amendment dated March 16, 2025, and received March 17, 2025, which constituted a complete response to our January 3, 2025, action letter.

This NDA provides for the use of Subvenite (lamotrigine) oral suspension for the following indications:

Epilepsy—adjunctive therapy in patients aged 2 years and older:

- partial-onset seizures
- primary generalized tonic-clonic (PGTC) seizures
- generalized seizures of Lennox-Gastaut syndrome.

Epilepsy—monotherapy in patients aged 16 years and older:
Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug.

Bipolar disorder:
Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in patients treated for acute mood episodes with standard therapy.

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.

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) 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 via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on July 21, 2025, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 218879**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Subvenite (lamotrigine) oral suspension shall be 24 months from the date of manufacture when stored at 20°C to 25°C.

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.

We are waiving the pediatric studies requirement for ages 0 to less than 1 month in patients with epilepsy because necessary studies are impossible or highly impracticable and because the product does not represent a meaningful therapeutic benefit over

[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.

existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this group. Patients ages 0 to less than 1 month usually require an intravenous formulation, and the long titration period of this product (about 6 weeks) would delay attainment of adequate drug levels.

We are waiving the pediatric studies requirement for ages 0 to 9 in patients with bipolar disorder because necessary studies are impossible or highly impracticable in this age group. It is difficult to reliably diagnose bipolar disorder in this age group.

This product is appropriately labeled for use in patients 2 to less than 17 years of age with epilepsy. We note that the pediatric studies requirement for ages 10 to less than 17 years of age in patients with bipolar disorder has been fulfilled. Therefore, no additional studies are needed in these pediatric age groups.

We are deferring submission of your pediatric studies for ages 1 month to less than 2 years in patients with epilepsy for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

4884-1 Conduct a study to evaluate the pharmacokinetics, safety, and tolerability of an age-appropriate formulation of lamotrigine oral suspension (Subvenite) to determine a dosing regimen for partial-onset seizures in pediatric patients 1 month to less than 2 years of age. The study should identify the drug exposure that is similar to the exposure that is effective in patients 2 years and older with partial-onset seizures.

Draft Protocol Submission:	03/2026
Final Protocol Submission:	07/2026
Study Completion:	07/2028
Final Report Submission:	01/2029

4884-2 Conduct a long-term open-label safety study of lamotrigine oral suspension (Subvenite) in pediatric patients 1 month to 2 years of age.

Draft Protocol Submission:	03/2026
Final Protocol Submission:	01/2029
Study Completion:	01/2031
Final Report Submission:	07/2031

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your IND 140073, with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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.*[4]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[7].

If you have any questions, contact Kelly Ross, Regulatory Health Project Manager via email at Kelly.Ross@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Emily Freilich, MD
Director
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[7] https://www.uspnf.com/

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/

EMILY R FREILICH
09/16/2025 03:38:00 PM
on behalf of DN2