CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218879Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 218879

MEETING REQUEST-
WRITTEN RESPONSES

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

Dear Mr. Sudhakar:[1]

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Subvenite (lamotrigine) oral suspension.

We also refer to your submission dated October 10, 2023, containing a meeting request. The purpose of the requested meeting was to obtain Agency's acceptance for filing the NDA with 6 months accelerated stability and controlled room temperature conditions as a rolling review of the NDA.

Further reference is made to our Meeting Granted letter dated October 19, 2023, wherein we stated that written responses to your questions would be provided in lieu of a meeting.

The enclosed document constitutes our written responses to the questions contained in your October 29, 2023 background package.

If you have any questions, please contact Erica Keafer, Regulatory Business Process Manager at 301-796-1435 or erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Julia Pinto, Ph.D.
Branch Chief
Division of New Drug Products II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

[1] 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.

Enclosure:

- Written Responses

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

WRITTEN RESPONSES

Meeting Type: B

Meeting Category: Pre-NDA, Chemistry - Other

Application Number: NDA 218879

Product Name: Subvenite (lamotrigine) oral suspension

Indication: Treatment for Bipolar Disorder and Epilepsy

Applicant Name: OWP Pharmaceuticals, Inc.

Regulatory Pathway: 505(b)(2) of the Federal Food, Drug, and Cosmetic Act

1.0 BACKGROUND

OWP Pharmaceuticals, Inc. is developing a new dosage form of lamotrigine oral suspension for the treatment of epilepsy and bipolar disorder. The Applicant is preparing to file a 505(b)(2) with pre-assigned NDA 218879 as agreed in with PIND 140073.

On October 10, 2023, the Applicant requested a type B, Pre-NDA meeting to obtain Agency's acceptance for filing the NDA with 6 months accelerated stability and controlled room temperature conditions as a rolling review of the NDA.

2.0 QUESTIONS AND RESPONSES

The sponsor's questions are reproduced below, and FDA's responses follow each question.

Question 1: *The firm intends to file the NDA with 6 months accelerated stability and controlled room temperature conditions for a rolling review request. Would this be an acceptable approach for filing this NDA?*

FDA Response to Question 1:

We acknowledge your intent to request rolling review of your planned NDA submission, with review of the CMC portion of your marketing application. Please note that only products with either Fast Track designation or Breakthrough Therapy designation are

eligible to be granted a Rolling Review for a marketing application. Currently, your application does not have either designation, therefore, is not eligible for Rolling Review. For further information regarding both of these designations, please refer to the guidance for industry *Expedited Programs for Serious Conditions – Drugs and Biologics*. https://www.fda.gov/RegulatoryInformation/Guidances/default.htm. This document may be requested from the Office of Communications, Division of Drug Information at 301-796-3400 or 1-888-463-6332.

From a CMC perspective, you propose to provide only 6 months of stability at the time of NDA submission. It should be noted that while we will accept additional data within the first 30 days of NDA submission, we cannot guarantee review of any additional data submitted during the review cycle due to our internal review timelines. Per ICH Q1E, if less than 12 months of data for three primary stability batches is provided, then extrapolation will not be possible and the assigned expiry will be based on the actual amount of data received, e.g., 6 months of long-term stability data would support a 6 month expiry. For more information, refer to ICH Q1A (R2) Guidance “Stability Testing of New Drug Substances and Products.” Additionally, it is premature to assess any retest or expiry of a proposed drug product at this time.

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/

JULIA C PINTO
12/04/2023 02:58:30 PM