NDA 210730

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Trevena, Inc.
c/o Syner-G BioPharma Group
Attention: Rachel L. Capone, MSHS
Regulatory Affairs Manager
100 Pennsylvania Avenue, Suite 310
Farmington, MA 01701

Dear Rachel Capone:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Olinvyk (oliceridine) injection, which was approved on August 7, 2020.

The Agency has determined that you have failed to meet the post marketing requirements (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for the following PMRs which were deferred until the dates listed:

PMR 3902-1, deferred until June 30, 2023
PMR 3902-2, deferred until June 30, 2023
PMR 3902-5, deferred until January 31, 2022
PMR 3902-6, deferred until October 31, 2022

Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDA with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, contact Jane Mun, Regulatory Project Manager, at jane.mun@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine,
and Pain Medicine
Office of Neuroscience
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/

RIGOBERTO A ROCA
05/10/2024 09:59:15 AM