



Trevena, Inc.
2870 Peachtree Road, Suite 502
Atlanta, GA 30305

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

October 30, 2025

Leah Crisafi, M.D., Director
Food and Drug Administration
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research
Attention: Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: NDA No. 210730; Sequence No. 0108
OLINVYK® (oliceridine) injection, for intravenous use, 1mg/mL
Response to PREA Non-Compliance Letter; Deferral Extension Requested

Dear Dr. Crisafi:

Reference is made to Trevena, Inc. ("Trevena") NDA 210730 for OLINVYK® (oliceridine) injection, for intravenous use, approved by the FDA on August 07, 2020 and to the Notification of Non-Compliance with PREA letter (Reference ID: 5661488) dated September 18, 2025 for the following postmarketing study:

PMR 3902-3 – Conduct a randomized, controlled trial evaluating the pharmacokinetic, pharmacodynamic, safety, tolerability, and efficacy profiles of OLINVYK in pediatric patients aged birth to less than 3 years of age for who parenteral opioid therapy is warranted.

The purpose of this submission is to provide Trevena's response to the Notification of Non-Compliance with the PREA referenced above and request a release of (b) (4) PREA PMRs. The response and request for release is included in [Module 1.17.2](#) Correspondence Regarding Postmarketing Requirements and includes an explanation for the delay and request. Alternatively, Trevena is requesting deferral extensions (b) (4) PREA PMRs. The request is included in [Module 1.9.2](#) Request for Deferral of Pediatric Studies.

The confidentiality of this submission, and all information contained herein, is claimed by Trevena, Inc. under all applicable laws and regulations. Disclosure of any such information is not authorized without the prior written authorization of Trevena, Inc.

If you have any questions regarding this submission, please contact me at 215-565-5752, or via email at cbourdow@trevena.com.



Trevena, Inc.
2870 Peachtree Road, Suite 502
Atlanta, GA 30305

Sincerely,

A handwritten signature in dark ink that reads 'Carrie L. Bourdow' in a cursive script.

Carrie L. Bourdow
Trevena, Inc., Acting CEO
(P) 215-565-5752
(E) cbourdow@trevena.com

This submission is being submitted in eCTD format. This electronic submission is approximately 8.05 MB in total size. All files were checked and verified to be free of viruses prior to being sent via the Electronic Submissions Gateway using CrowdStrike Antivirus version 7.28.20008.0.