



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](mailto:cbourdow@trevena.com).



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

Sincerely,

*Carrie L. Bourdow*

Carrie L. Bourdow  
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