



CONFIDENTIAL

July 3, 2025

Leah Crisafi, MD Director  
Center for Drug Evaluation and Research  
Food and Drug Administration Division of Anesthesia,  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

RE: **NDA 214044, Sequence 0085**  
**QDOLO (tramadol hydrochloride) oral solution, 5 mg/mL**  
**RESPONSE TO PREA NON-COMPLIANCE LETTER**  
**DEFERRAL EXTENSION REQUESTED**

Dear Dr. Crisafi:

Reference is made to New Drug Application (NDA) 214044 for QDOLO® (tramadol hydrochloride) Oral Solution, approved on September 9, 2020, as well as Investigational New Drug (IND) Application 127021, both held by Athena Bioscience LLC. The product is indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Reference is also made to Postmarketing Requirement (PMR) 3918-1 for the characterization of the impact that tramadol has on brain development in order to support pediatric dosing in adolescent patients 12 to less than 17 years of age.

This correspondence is submitted in response to the “[Notification of Non-Compliance with PREA](#)” Letter from the FDA dated May 22, 2025. This submission includes Athena Bioscience’s formal written response to the non-compliance letter and a deferral extension request for the pediatric assessment required for PMR 3918-1. The extension request is provided in [Section 1.9.6](#) and includes the reasons for the delayed pediatric assessment and the date by which we expect to submit the assessment. This submission meets the 45-calendar day timeline defined in Section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act.

Please be advised that material and data contained in this submission are confidential. The legal protection of such confidential material is hereby claimed under applicable provisions of *18 U.S.C., Section 1905 (Disclosure of Confidential Information Generally) or 21 U.S.C., Section 331 (J) (Prohibited acts)*. Disclosure of any such information is not authorized without the prior written authorization of Athena Bioscience, LLC.



If there are any questions pertaining to the content of this submission, please contact me using the information below.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jeff Bryant".

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