June 07, 2024
NDA 214044 : SN0074
RESPONSE TO PREA NON-COMPLIANCE LETTER

Rigoberto Roca, M.D. Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: **NDA 214044, Sequence 0074**
QDOLO (tramadol hydrochloride) oral solution, 5 mg/mL
RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Roca:

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 received from the FDA on May 14, 2024, and dated April 25, 2024. This submission includes Athena Bioscience's formal written response to the non-compliance letter and a deferral extension request for the juvenile animal toxicity study 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.

This submission is in eCTD format, with full electronic functionality in accordance with," *M4*

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Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use M4 (dated October 2017) and has been compiled in accordance with the Agency's draft guidance for industry, *"Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications"* (February 2020, Revision 7). This submission will be submitted electronically to the Agency via FDA Gateway.

The files in this submission have been scanned with Webroot Secure Anywhere Business Endpoint Protection v9.0.35.17 and no viruses have been detected. The estimated size of this application is 5 MB.

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

Sincerely,

Ruth Collins

Digitally signed by rcollins@sovpharm.com
Date: 2024.06.07 14:34:32 -05'00'

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