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March 20, 2026

Dr. Emily Freilich, M.D.
Office of Neuroscience
Division of Neurology 1
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
via Electronic Submission Gateway

**Re: NDA # 214679; eCTD Sequence # 0071
EPRONTIA[®] (topiramate) Oral Solution, 25 mg/mL
Response to PREA Non-Compliance Letter**

Dear Dr. Freilich,

Reference is made to NDA 214679 for EPRONTIA[®] (topiramate) Oral Solution, 25 mg/mL approved by the Agency on November 5, 2021 and the Notification of Non-Compliance with PREA, dated 03 February 2026. Azurity Pharmaceuticals, Inc. (Azurity) submits this response to the Notification of Non-Compliance with PREA in accordance with the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c(d)(1)].

Reference is made to the original PMR 4169-1 issued in the Approval letter for NDA 214679, stated as follows:

A randomized, double-blind, placebo-controlled efficacy and safety study under PREA to evaluate topiramate oral solution for the preventive treatment of migraine in children 6 through 11 years of age. This efficacy study must be designed to demonstrate superiority of topiramate oral solution over placebo.

Final Protocol Submission: 03/2022

Study Completion: 06/2025

Final Report Submission: 12/2025

An initial draft protocol for PMR 4169-1 was submitted to FDA for review on June 22, 2022. Agency comments to the draft protocol were communicated on January 26, 2023. Azurity updated the protocol as per the FDA suggestions and submitted the final protocol on February 21, 2023. The FDA subsequently issued the Acknowledge Final Protocol for Postmarketing Requirements letter dated June 9, 2023. After the acknowledgement of the final protocol was received, Azurity submitted the chemistry, manufacturing, and controls information for the drug product to be used in the clinical study on June 28, 2023. Following communications with the FDA on December 5-6, 2023, the final study protocol was resubmitted on December 8, 2023. An Information Request was then received from the Agency on December 18, 2023, requesting additional information and

updates to the investigational drug label to which Azurity provided response on December 20, 2023. On January 4, 2024, FDA communicated an additional Information Request which included proposed further revision of the clinical protocol. Azurity revised the protocol according to the proposed FDA revisions and submitted the revised protocol on the same day (January 4, 2024). After submission of the revised final protocol, the Study May Proceed letter was provided to Azurity dated February 2, 2024.

Azurity began working to identify a contract research organization (CRO) to conduct the study and reached out to several organizations in August 2022. However, the CROs cautioned of challenges identifying relevant clinical sites for participation in the study, based upon previous experiences with similar trials. Many of the sites surveyed during the preliminary review stage were already participating in ongoing migraine studies in the targeted pediatric population. This lack of available sites led to further delays in identifying a CRO and initiating the study.

In light of the challenge of identifying sites willing to participate in the study and the most recent FDA mandated safety revisions to the Warnings and Precautions section (Safety Labeling Change Notification, dated October 24, 2025) to the package insert (PI), Azurity has reassessed the viability of the study in the pediatric patient population and commits to submitting a (b) (4) (b) (4) (b) (4) on or before June 12, 2026. Please note that Azurity submitted a Prior Approval Supplement to update the PI per the FDA recommended safety updates on November 19, 2025.

We request that information related to this application be treated as confidential within the meaning of 21 CFR 314.430, and that no information, except as provided in 21 CFR 314.430, be released without prior consent of the applicant.

This submission is organized in accordance with the Agency's Guidance, "Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications (September 2024)" and "Providing Regulatory Submissions in Electronic Format - General Considerations (January 1999)".

Should you have any questions concerning this submission, please contact Justin Kilby by e-mail at rasa@azurity.com. Alternatively, you may contact Felicia Bullock, Senior Director, Head of Regulatory Affairs at rasa@azurity.com.

Sincerely,

Justin Kilby
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Justin Kilby
Associate Director, Regulatory Affairs