AUCTA PHARMACEUTICALS

June 11, 2026

RESPONSE TO PREA NON-COMPLIANCE LETTER/ DEFERRAL EXTENSION REQUESTED NDA 216185; Seq. 0124

Central Document Room
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room (CDR)
5901B Ammendale Road
Beltsville, MD 20705-1266

Re: NDA 216185 / SEQUENCE # 0124
Motpoly XR (Lacosamide) Extended-Release Capsules, 100 mg, 150 mg and 200 mg
Submission: Response to PREA Non-Compliance Letter
Submission: Deferral Extension Requested

Dear Sir/Madam,

Reference is made to New Drug Application (NDA) 216185 for Motpoly XR (lacosamide) Extended-Release Capsules, 100 mg, 150 mg and 200 mg, approved on May 04, 2023. Motpoly XR is indicated for the treatment of partial-onset seizures, and as adjunctive therapy for primary generalized tonic-clonic seizures, in adults and pediatric patients weighing at least 50 kg.

Reference is also made to Investigational New Drug (IND) Application 140785 and PMR 4437-1.

Further reference is made to FDA's 28 April 2026 Notification of Non-Compliance with PREA.

The purpose of this submission is to provide a response to the 28 April 2026 Notification of Non-Compliance with PREA and to request a deferral for PMR 4437-1.

This submission is composed of the cover letter, FDA Form 356h, 1.17.2 (Response to PREA Letter), 1.9.2 (Deferral Extension Request).

Patent Verification (MAA)
The proposed change described in this amendment is not one of the types of amendments described in 21 CFR 314.60(f)(1).

This submission is being submitted in eCTD format. All files were checked and verified to be free of viruses using current antivirus software prior to being sent via the Electronic Submissions Gateway. If further information is needed or if there are questions regarding this request, please contact us at (732) 652-9230 or reg.affairs@auctapharma.com.

Sincerely,

Yanfang Liu

Digitally signed by Yanfang Liu
Date: 2026.06.11 13:25:02 +08'00'

For: Yujin Bi
Regulatory Affairs Director

Aucta Pharmaceuticals, Inc.
170 Mt Airy Rd | Basking Ridge, NJ 07920 | Email: reg.affairs@auctapharma.com