December 7, 2022

DEFERRAL EXTENSION REQUESTED

Nick Kozauer, MD, Director
U.S. Food and Drug Administration
Division of Neurology II, Office of Neuroscience
Center for Drug Evaluation and Research (CDER)
Central Document Control Room
10903 New Hampshire Ave
Silver Spring, Maryland 20993

Product Name:	**Cambia® (diclofenac potassium) 50 mg powder for oral solution**
NDA No.:	**022165**
Sequence No.:	**0188**
Subject:	**Deferral Extension Requested**

Dear Dr. Kozauer:

Reference is made to the Notification of Non-Compliance with PREA letter dated September 28, 2022. Additional reference is made to the Release and Reissue PMR letter dated June 20, 2017 that was issued to Depomed, Inc.

Since assuming sponsorship of this NDA from Depomed, Inc., Assertio Therapeutics, Inc. (Assertio) has been working on progressing PMR 974-7 titled "*Deferred controlled safety and efficacy study under PREA for the acute treatment of migraine with or without aura in pediatric patients ages 6-17 years old with a PK run-in phase and a 12 month open-label long-term safety extension*."

Assertio has started developing a new formulation for the pediatric patients ages (b) (4) years old. The formulation being pursued is (b) (4) The formulation variations under development are being evaluated for physical, chemical, and microbial stability to ensure suitability for use in clinical studies. This development work is taking longer than initially anticipated.

Assertio therefore respectfully requests a deferral extension to the following schedule:

Draft Protocol Submission:	09/2023
Final Protocol Submission:	06/2024
Study Completion:	06/2028
Final Report Submission:	12/2028

Assertio takes the pediatric PMR for Cambia under NDA 022165 very seriously and has progressed diligently with the planning and conduct of this study since assuming NDA sponsorship. Assertio is committed to working with the Agency towards the timely completion of the assigned PMR under NDA [redacted] (b) (4) We appreciate the Agency's consideration of this request for deferral extension based on the described circumstances.

If you have any questions regarding this submission or require additional information, please do not hesitate to contact me at (224) 441-6390 or via email at RA@assertiotx.com

Sincerely,

Vasilios Iskos
Senior Vice President, Operations

Electronic Submission Specifications

This submission is compliant with FDA's Guidelines for Industry and current eCTD specifications.

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

Anti-Virus Program	Norton 360
Program Version	22.22.11.12
Virus Definition Date	December 7, 2022
Approximate Submission Size	< 5 MB

The technical point of contact for this submission is:

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