



NDA 022165

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Depomed, Inc.
Attention: Terry Lumati
7999 Gateway Blvd., Suite 300
Newark, CA 94560

Dear Ms. Lumati:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Cambia (diclofenac) powder for oral solution, which was approved on June 17, 2009.

The Agency has determined that you have failed to meet the postmarketing requirements (PMRs) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMRs 974-4, 974-5, and 974-6, which were deferred until December 31, 2016.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a “**DEFERRAL EXTENSION REQUESTED**” in your response. We note that you requested deferral extensions on April 16 and August 14, 2013; however, we have determined that your requests did not qualify for an extension.

In accordance with FDASIA, FDA will post this letter and your response on the website located at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a “**RESPONSE TO PREA NON-COMPLIANCE LETTER.**” To facilitate our review, submit this information to your NDA with a cross-reference letter to the IND to which your protocol has been submitted.

If you have any questions, call Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC P BASTINGS
01/09/2017