



NDA 022202

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Depomed Inc.
Attention: Michelle P. Wong, Ph.D.
Associate Director, Regulatory Affairs
7999 Gateway Blvd, Suite #300
Newark, CA 94560

Dear Dr. Wong:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Zipsor (diclofenac potassium) Liquid Filled Capsules, which was approved on June 16, 2009.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR 1053-2, which was deferred until June 30, 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 a deferral extension on March 23, 2016; however, we have determined that your request 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 Mavis Y. Darkwah, Pharm.D., Regulatory Project Manager, at (240) 402-3158.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Director
Division of Anesthesia, Analgesia
and Addiction Products
Office of Drug Evaluation II
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/

SHARON H HERTZ
07/07/2016