DEPOMED

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August 01, 2016

RESPONSE to PREA NON-COMPLIANCE LETTER

Sharon Hertz, MD, Division Director
Division of Anesthesia, Analgesia and Addiction Products (DAAAP)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Product Name:	**Zipsor® (diclofenac potassium) Liquid Filled Capsules, 25 mg**
NDA No.:	**022202**
Sequence No.:	**0088**
Submission Type:	**Response to PREA Non-Compliance Letter**

Dear Dr. Hertz:

Reference is made to the Deferral Extension Request by Depomed, Inc. (Depomed) on March 23, 2016 regarding the deferred pediatric assessment PMR 1053-2 assigned to NDA 022202 under the Pediatric Research Equity Act (PREA). Reference is also made to FDA's denial of this request and subsequent Notification of Non-Compliance with PREA letter, dated July 7, 2016. Depomed is hereby responding to the Agency's Non-Compliance letter.

In accordance with the Post Marketing Requirement PMR 1053-2, Depomed is requested to complete the pharmacokinetics and safety study of Zipsor in pediatric patients ages 2-12 years with mild to moderate acute pain by December 31, 2015 and to submit the final study report by June 30, 2016. Depomed has completed the above study and plans to submit the final study report in (b) (4) Depomed encountered significant enrollment challenges during the conduct of this study. We are working diligently towards the completion of the final report. We recognize the importance of the PREA program and commit to fulfill this requirement as soon as possible.

If you have questions concerning this correspondence, please do not hesitate to contact me at (510) 744-8000 or via email at RA@depomed.com.

Sincerely,

Michelle P. Wong, Ph.D.
Associate Director, Regulatory Affairs

cc: Pediatric and Maternal Health Staff, Center for Drug Evaluation and Research

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