Depomed

7999 Gateway Blvd., Suite 300, Newark, CA 94560
T 510.744.8000 | F 510.744.8001
www.depomed.com

February 26, 2015

Sharon Hertz, MD, Acting Director
Attention: Swati Patwardhan, Sr. Regulatory Health Project Manager
Division of Anesthesia, Analgesia and Addiction Products
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Product Name:	**Zipsor® (diclofenac potassium) Liquid Filled Capsules, 25 mg**
NDA #:	**022-202**
Cross Reference to IND #:	**63,308**
Sequence #:	**0082**
Subject:	**RESPONSE TO PREA NON-COMPLIANCE LETTER**

Dear Dr. Hertz:

Reference is made to the PREA Non-Compliance Letter dated January 28, 2015, received by Sponsor on February 06, 2015. Reference is also made to the Agency's "Deferral Extension Granted" correspondence dated April 12, 2013.

Further references are made to the following submissions:

- Submission Sequence 0077, final study report for study 81-0072 (PREA 1053-1) submitted on November 7, 2014 under IND 63,308.
- Submission Sequence 0081, for the same final study report submitted on February 12, 2015 under NDA #022-202.

The purpose of this letter is to respond to the PREA Non-Compliance Letter. A deferral extension is not deemed to be applicable in this situation, as the appropriate study report has already been submitted to the Agency under the above referenced IND and NDA. To serve as a cross-reference per the Agency's request, a copy of this response letter will be sent to IND #63,308 as a paper submission (Sequence 0083).

In response to this notification, the Sponsor notes that it had submitted the final study report, both to the IND (prior to the December 15, 2014 date per the Deferral Extension Granted request) as well as the NDA (date noted above and prior to the Sponsor's knowledge or receipt of the PREA non-compliance letter). The Sponsor acknowledged, in Agency communications, that Sequence 0077 should have been submitted to the NDA and rectified this by subsequently submitting the same report to the NDA (Sequence 0081).

From the Sponsor's perspective, the focus of the provisions of title V, section 505, of the Food Drug Administration Safety and Innovation Act of 2012 (FDASIA), is on providing the necessary data to the FDA in a timely manner. There is no qualification that an IND submission (versus an NDA submission) would be considered as a failure to submit. The Sponsor believes its actions are in compliance with FDASIA.

Additionally, there is an inherent connection between the IND and NDA as even for this Non-Compliance Letter Response, the Sponsor was requested to submit this information to the IND as a cross-reference and to facilitate Agency review.

We truly respect the Agency's valuable time and recognize the importance of the PREA program. We acknowledge CDER's recommendation to submit PREA related reports to the NDA and have already completed this request.

For the reasons noted above, the Sponsor appreciates the Agency's review of this response and reconsideration for the issuance of the PREA Non-Compliance Letter. We would also request written confirmation that no further action is required from the Sponsor.

Please note that this correspondence contains confidential trade secrets, commercial, and financial information as per 21 CFR 20.61.

Should you have any questions regarding this submission, please do not hesitate to contact me at (510) 744-8000 or RA@depomed.com.

Sincerely,

Terry Lumati
Manager, Regulatory Affairs

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

Attachment: FDA Form 356h

Electronic Submission Specifications

This submission is compliant with FDA's Guideline for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway. This eCTD has been generated by Accenture, LLP (formerly Octagon Research Solutions Inc.), who has filed an acceptable eCTD pilot with the Center (Pilot Number 900777).

Anti-Virus Program	Symantec Endpoint Protection Edition
Program Version	11.0.5002.333
Virus Definition Date	**0**2/25/2015 rev. 1
Submission Size	Approx. 5.5 MB

The IT point of contact for this submission is:

Name	Terry Lumati
Phone Number	510.744.8000
Email Address	ra@depomed.com