



**NDA 204592 • ZORVOLEX® (diclofenac) CAPSULES • SEQUENCE NUMBER 0111 •
CORRECT SEQUENCE NUMBER 0110 COVER LETTER**

March 07, 2018

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

Re: NDA 204592 for Zorvolex® (diclofenac) Capsules

Dear Dr. Hertz:

Reference is made to NDA 204592 for Zorvolex® (diclofenac) Capsules, Sequence Number 0110 submitted on March 01, 2018. Sequence 0110 provided Iroko's response to the PREA NON-COMPLIANCE LETTER dated January 25, 2018 and also requested a DEFERRED EXTENSION for NDA 204592 Zorvolex Capsules. We are submitting an updated copy of the [Cover Letter for Sequence 0110](#) in order to correct an error in the proposed timeline dates.

The March 01, 2018 Cover Letter for Sequence 0110 included a proposed Pediatric Development Timeline for Zorvolex Capsules as part of the request for Deferral Extension. (b) (4)

Upon further review, we noted discrepancies between the stated intervals and the proposed dates listed in the development plan timeline table. The timeline dates proposed in the original Cover Letter (dated March 01, 2018) and the corrected Cover Letter for Sequence 0110 (dated March 07, 2018) are shown below.

Zorvolex Capsules Pediatric Development Plan Timeline

(b) (4)

A large rectangular area of the document is completely redacted with a solid grey fill, obscuring the content of the Pediatric Development Plan Timeline table.

This submission is provided entirely in eCTD (electronic Common Technical Document) format; therefore, no Table of Contents is being provided.



If you have any questions or require additional information regarding this submission, please do not hesitate to contact me, at 267.546.1428, or via email at jmolt@iroko.com.

Sincerely,

James T. Molt, Ph. D

Digitally signed by James T. Molt, Ph. D
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