



**NDA 204592 • ZORVOLEX® (diclofenac) CAPSULES • SEQUENCE NUMBER 0110 •  
RESPONSE TO PREA NON-COMPLIANCE LETTER • DEFERRAL EXTENSION  
REQUEST**

March 01, 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  
Submission of PREA Deferral Extension Request and Response to PREA non-  
compliance letter**

Dear Dr. Hertz:

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[21 U.S.C. 355c(d)(1)], Iroko is responding to your [PREA NON-COMPLIANCE LETTER](#) dated January 25, 2018 and also requesting a DEFERRAL EXTENSION for NDA 204592 Zorvolex Capsules.

Submission of study 2091-2 was delayed due to failure to establish an agreed upon resubmission date following our original request for deferral (NDA 204592; Sequence 0096) submitted January 6, 2017. There were several email exchanges with the agency dated February 23, March 8 (2), May 18 (2), and May 19, 2017, in which FDA asked Iroko to justify a proposed deferral extension but no date was agreed and January 6, 2018 remained as the final report submission date.

[REDACTED] (b) (4)

In an email on November 21, 2017 FDA agreed with Iroko's proposal to submit a request for a Type C meeting to discuss issues concerning the original PREA program for Zorvolex. However, FDA disagreed with Iroko's suggestion [REDACTED] (b) (4) and stated that we should request a deferral extension.

Therefore, with this letter, Iroko is requesting a DEFERRAL EXTENSION for Zorvolex PREA [REDACTED] (b) (4) 2091-2 [REDACTED] (b) (4) according to the following timeline:



## Zorvolex Capsules Pediatric Development Plan Timeline



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](mailto:jmolt@iroko.com).

Sincerely,

**James T. Molt, Ph. D**

Digitally signed by James T. Molt, Ph. D  
DN: cn=James T. Molt, Ph. D, o=Regulatory Affairs,  
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