NDA 204768 • TIVORBEX® (indomethacin) CAPSULES • SEQUENCE NUMBER 0119• RESPONSE TO PREA NON-COMPLIANCE LETTER

July 10, 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 204768 for Tivorbex® (indomethacin) Capsules
Response to PREA non-compliance letter

Dear Dr. Hertz:

Under the provisions of section 505B(d)(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[21 U.S.C. 355c(d)(l)], Iroko is responding to your PREA NON-COMPLIANCE LETTER dated June 19, 2018.

Postmarketing Requirement (PMR) Study 2128-2 remained scheduled for June 1, 2018 after a request for deferral (Sequence 0112 submitted March 8, 2018) was denied.

The June 1, 2018 date was missed due to issues with developing an acceptable pediatric formulation of Tivorbex. Iroko has had an ongoing dialog with the Division about this issue that has resulted in establishment of a Type C meeting on November 28, 2018.

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,

J.T. Molt, Ph.D

Digitally signed by J.T. Molt, Ph.D
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