

NDA 210607

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

60 Degrees Pharmaceuticals, INC
c/o Fast-Track Drugs & Biologics, LLC
Attention: Janet H. Ransom, Ph.D.
President
20010 Fisher Avenue, Suite G
Poolesville, MD 20837

Dear Dr. Ransom:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Arakoda (tafenoquine) tablet, which was approved on August 8, 2018.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for:

PMR 3464-1, which was deferred until June 30, 2025.

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)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a **“DEFERRAL EXTENSION REQUESTED”** in your response. We note that you requested a deferral extension on July 28, 2025, and it is currently under review.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at <https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a **“RESPONSE TO PREA NON-COMPLIANCE LETTER.”** To facilitate our review, submit this information to your NDA with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, contact Lori Kolejian, Regulatory Project Manager, at 301-796-0881 or email Lori.Kolejian@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PETER W KIM
09/08/2025 04:32:18 PM