



NDA 209483

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Primus Pharmaceuticals Inc.
C/O Prosoft Clinical
Attention: Robert W. Babilon, Consultant
851 Duportail Road, 2nd Floor
Chesterbrook, PA 19087

Dear Robert W. Babilon:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Impoyz (clobetasol propionate) Cream, which was approved on November 28, 2017.

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 3310-1, which was deferred until December 31, 2023.

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. We note that you requested a deferral extension on January 5, 2024.

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 Qianyiren Song, Regulatory Project Manager, at (301) 796-2581 or qianyiren.song@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
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/

TATIANA OUSSOVA
02/21/2024 10:14:28 AM