



Primus Pharmaceuticals, Inc.  
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August 23, 2023

Shari Targum, MD  
Director (Acting)  
Division of Dermatology and Dentistry  
Office of Immunology and Inflammation (OII)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**Re: NDA 209483**  
**IMPOYZ® (clobetasol propionate) Cream, 0.025%**  
**Sequence No: 0088**  
**Subject: RESPONSE TO PREA NON-COMPLIANCE LETTER**  
**PREA DEFERRAL EXTENSION REQUESTED**

**Cross Reference**  
**IND 110799**  
**Sequence 0055**

Dear Dr. Targum,

Reference is made to the "Notification of Non-Compliance with PREA" letter dated July 26, 2023 (ref ID 5215122). The Agency letter stated that the postmarketing requirement (PMR) 3310-1 had not been met, as the pediatric assessment had not yet been submitted. This requirement had been deferred to May 31, 2020.

The Agency letter required a response within 45 calendar days, with the response to include the reasons for the delayed pediatric assessment, along with a date by which the assessment is expected to be submitted. A deferral extension may also be included in the response.

Please note that Primus Pharmaceuticals Inc. (Primus) assumed the responsibilities to address this pediatric assessment as a result of an asset purchase agreement from the previous sponsor of this NDA. At the time of the purchase, the enrollment phase in this clinical study had already been terminated due to the difficulties experienced in enrolling pediatric subjects in the 6 to 12 year old age group in this HPA Axis Suppression study.

Primus takes this pediatric PMR for Impoyz Cream under NDA 209483 very seriously. We are therefore requesting a deferral extension to December 15, 2023, to address the issues raised in the PREA Non-Compliance letter. We propose to submit a final report and proposed labeling change on or before that date.



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We appreciate the Agency's consideration of this request.

If you have any questions or require additional information regarding this submission, please contact me via phone at 480-483-1410 (office) or via email at [jweir@primusrx.com](mailto:jweir@primusrx.com)

Sincerely,

A handwritten signature in black ink that reads 'JD Weir'.

JD Weir  
CEO

Primus Pharmaceuticals Inc.

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