NDA 208079

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Primus Pharmaceuticals, Inc.
Attention: Robert W. Babilon
President
996 Old Eagle School Road, Suite 1106
Wayne, PA 19087

Dear Mr. 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 Sernivo (betamethasone dipropionate) topical spray, 0.05%, which was approved on February 5, 2016.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application. We have reviewed your submission and conclude that the terms of the requirement were not met. We have determined that the data included in the final report submission does not adequately fulfill the postmarketing requirement for PMR 3016-1, which was deferred until July 31, 2018. Therefore, we are hereby notifying you that due to your failure to submit either a complete pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

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.

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, call LT Sascha Randolph, BSDH, PHDHP, USPHS, Regulatory Project Manager, at (301) 796-2110.

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
03/16/2022 02:39:26 PM