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April 22, 2022

Kendall Marcus, MD
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Food and Drug Administration
5901 B Ammendale Road
Beltsville, MD 20705 1266

Re: **NDA 208079** (b) (4)
SERNIVO® (betamethasone dipropionate) Spray, 0.05%
Sequence No: **SN0078**
Subject: **RESPONSE TO PREA NON-COMPLIANCE LETTER**
PREA DEFERRAL EXTENSION REQUESTED

Cross Reference: IND 104853, Sequence 0067

Dear Dr. Marcus,

Reference is made to the (b) (4) as described by the Post Marketing Requirement (PMR) 3016 1, as amended. (b) (4) submitted as "Submission of Required Pediatric Assessments".

Reference is also made to the "Notification of Non-Compliance with PREA" letter received on March 16, 2022 (reference ID 4953827). This Agency letter stated that the data included in the final report submission did not adequately fulfill the postmarketing requirement (PMR) 3016 1, which had been deferred until July 31, 2018.

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, this clinical study had already been terminated due to the difficulties experienced in receiving permission from the parents (guardians) of an adequate number of pediatric subjects to enroll in and complete this HPA Axis Suppression study. Apparently, the vast majority of the parents were not willing to subject their minor children to the safety risks associated with the test and multiple blood draws necessary to measure HPA Axis Suppression. A previous sponsor had communicated with the Agency frequently to provide status updates with outlines of the exhaustive measures taken to increase subject enrollment. These issues were submitted to (b) (4) with a request to extend the pediatric study timelines under CTD Module 1.9.4 Proposed Pediatric Study Request (April 12, 2018, SN0053) and followed up with a submission to Module 1.12.9 Notification of Discontinuation of Study (February 21, 2019, SN 0057).

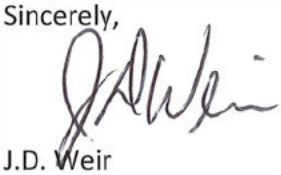
Upon receipt of this NDA from the previous sponsor, Primus submitted all available information (b) (4) to notify the Agency of the extent of the collected pediatric experience, which was limited to 3 pediatric subjects.

Primus takes this pediatric PMR for Sernivo Spray under NDA 208079 very seriously. We are therefore requesting a deferral extension to April 28, 2023, to address the issues raised in the PREA Non-Compliance letter. We are hopeful in the potential to enroll the reduced number of subjects within this timeframe, however, the effects of the COVID pandemic are expected to continue to be possibly complicating factors to meeting enrollment timelines.

We appreciate the Agency's consideration of this request, and we recognize your acknowledgment of the difficulty in enrolling pediatric subjects as per the reduced enrollment requirements identified in the letter received.

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

Sincerely,



J.D. Weir
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Primus Pharmaceuticals Inc.

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Electronic Submission Specifications

This submission is compliant with FDA's Guidelines for Industry and current eCTD specifications.

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

Anti-Virus Program	Symantec Endpoint Protection Edition
Program Version	14.2.4814.1101
Virus Definition Date	04/21/2022 r23
Submission Size	Approx. 3.24 MB

The IT point of contact for this submission is:

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