August 11, 2017

Tatiana Oussove, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Food and Drug Administration
White Oak Building 22, Room: 5350
10903 New Hampshire Avenue
Silver Spring, Maryland

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

NDA 022563/S-002; Sequence 107
Sorilux® (calcipotriene) Foam, 0.005%

Dear Dr. Oussove,

On July 17, 2017, the FDA issued a Notification of Non-Compliance with the postmarketing requirement (PMR) of the Pediatric Research Act (PREA) for this application because Mayne Pharma LLC (Mayne Pharma) had not yet submitted its pediatric assessment for PMR 1944-1: "A Pharmacokinetics/ Pharmacodynamics trial of Sorilux Foam, 0.005% under maximum use conditions in 20 evaluable pediatric subjects with plaque psoriasis of the scalp and body age 12 years to 16 years and 11 months. Evaluate the effect of the product on calcium in all subjects (STF115750)." The final report submission was due June 30, 2017 (deferral extension request granted December 30, 2014).

Mayne Pharma is fully committed to completing the postmarketing requirements for Sorilux Foam, 0.005%. To that end, when Mayne acquired ownership of NDA 022563 on January 9, 2017 it promptly began a review of Study STF116750, the study addressing commitment PMR 1944-1. Based on that review, Mayne Pharma concluded that the study could be closed. Since Mayne Pharma was not previously party to discussions with the FDA concerning the post-marketing pediatric study requirements for Sorilux Foam, it decided to submit a Type B Meeting Request on May 22, 2017 to seek, among other things, concurrence from the FDA that it was appropriate to close Study STF116750.

In the same meeting request, Mayne Pharma asked the FDA whether it could extend the submission date for the final study report for PMR 1944-1 under the mistaken belief that this request addressed Mayne Pharma's commitment to fulfill its pediatric assessment for PMR 1944-1. Mayne Pharma now recognizes that a Meeting Request was not the appropriate forum for requesting a submission date extension. Accordingly, provided in module 1.9.2 is a formal

request for a Deferral Extension until January 30, 2018 to submit the final study report for PMR 1944-1. A cross-reference letter is being submitted to IND 071198.

Should you have any questions or require additional information, please contact the undersigned directly on (225) 315-6173 or via email at terri.nataline@maynepharma.com.

Sincerely,

Terri Nataline

Terri Nataline
Vice President, Regulatory Affairs

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LETTER OF NON-REPUDIATION

Mayne Pharma LLC is confirming that a Letter of Non-Repudiation is on file with the Agency. This letter was provided on August 04, 2016 to Ms. La Misha Fields at the Electronic Submissions Gateway.

Susan Canady

Senior Regulatory Affairs Specialist

04 Aug 2016

Date

mayne pharma

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The IT point of contact for this submission is:

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