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16 April 2025

CDR Trang Tran, PharmD, MBA, BCPS, Senior Regulatory Project Manager
Shannon Liu, DPT, Regulatory Project Manager
Division of Regulatory Operations for Nonprescription Drugs I
Office of Regulatory Operations
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: MGF 400105 – Response to FDA Advice Letter dated 4-14-2025 [3522]

Dear Trang and Shannon,

Reference is made to our monograph file (MGF) 400105 and the teleconference held between FDA and DSM on April 4, 2025. During this teleconference, FDA reiterated its concerns with DSM's study methodology as noted in Information Requests (IRs) #6, #11, and #14, issued on November 20, 2024, January 22, 2025, and March 5, 2025, respectively.

FDA indicated that it would provide written comments to DSM's submission received on April 2, 2025, which contained the draft protocol for an SPF efficacy study. On April 11, 2025, DSM submitted an additional response to IR #14, which included revised draft protocols for SPF efficacy studies.

In its advice letter dated April 14, 2025, FDA provided several comments and recommendations regarding DSM's revised SPF test method.

We greatly appreciate the swift feedback provided during our teleconference on April 4, 2025, and in your advice letter dated April 14, 2025. Your comments and recommendations regarding our study methodology and proposed SPF test method have been invaluable.

Thank you for your prompt response to our SPF efficacy protocol submitted on April 11, 2025. We have carefully reviewed § M020.80 of the monograph and integrated your advice into our revised

draft protocols. Given the short window associated with the study's start, we will incorporate all advice and comments and follow up with the study protocols and specifics. We are pleased to inform you that the SPF study is scheduled to begin on April 16, 2025, and will run until May 9, 2025.

To ensure full compliance with FDA protocol requirements, we will have a dedicated study monitor overseeing the process. We will provide a comprehensive and compliant protocol, along with the study results, in our next communication. Complete reports are expected to be available by May 16, 2025.

We extend our sincere thanks to the FDA for the opportunity to discuss this matter further. We believe that the tests will be fully compliant with FDA requirements, ensuring the highest standards are met.

Thank you once again for your guidance and support. We look forward to continuing our collaborative efforts to achieve the best possible outcomes.

The response to this information request is being provided electronically under Mod 1 via FDA's NextGen portal MGF 400105.

Please contact me if you have any questions or need additional information.

Sincerely,

Carl D'Ruiz, MPH.
Senior Regulatory and Business Development Manager, Beauty & Care, NA