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21 August 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 IR #19 [3831]

Dear Trang and Shannon,

Reference is also made to our submissions received on September 23, 27, and 30, 2024, supporting a Tier 1 Over-the-Counter (OTC) Monograph Order Request (OMOR) for a Generally Recognized as Safe and Effective (GRASE) determination for bemotrizinol (BEMT) 6% as a new sunscreen active ingredient under FDA's OTC Monograph M020: Sunscreen Drug Products for OTC Human Use.

Further reference is made to FDA's Information Request (IR) letter dated August 1, 2025, and subsequent email clarification of August 6, 2025 concerning MGF 400105 and a request for a letter of authorization from BASF for the Tinosorb impurity data for lots Tinosorb® S, FAT 70'884/C #02464CL3 and Tinosorb® S, FAT 70'884/B #06484CL2 and for the GLP report titled "03_213 Tinosorb S GLP-Report A" submitted on May 5, 2025, to MGF 400105.

In response to IR19, attached please find the requested information submitted prior to the due date of August 27, 2025.

This response is being submitted electronically under Module 1 via FDA's NextGen portal.

Bemotrizinol (BEMT)

Please contact me if there are any further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl D'Ruiz". The signature is written in a cursive style with a large initial "C".

Carl D'Ruiz, MPH.

Senior Science, Advocacy and Business Development Manager, Beauty & Care, NA