MGF-400105
Bemotrizinol (BEMT)

2.3.I Introduction

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2.3 Introduction to the Quality Overall Summary

Bemotrizinol (BEMT) is being sponsored under this Tier 1 OMOR (MFG-400105) by DSM for inclusion in the OTC Sunscreen Monograph at a maximum concentration of 6 %. As part of the safety evaluation for sunscreen products, the FDA requests an assessment of the human systemic absorption of the sunscreen active ingredient be made via the conduct of a Maximum Usage Trial (MUsT) in humans (DHHS 2019). To satisfy this requirement, DSM conducted a study to assess the human systemic absorption of 6% BEMT under maximum use conditions. The study, titled: *Ultraviolet Filter Bemotrizinol (BEMT): Clinical Pharmacokinetics Evaluation in a Topical Maximum Usage Trial (MUsT – Protocol Number BEMT-001),* was a single center clinical study conducted in 2 parts (Part 1: pilot study and Part 2: pivotal study).

It is our intention to address the data gaps identified by the FDA as being necessary for making a GRASE determination for BEMT's inclusion in the sunscreen monograph, using market image formulations. DSM's does not intend to file an NDA for a BEMT-based drug product. According to the FDA written comments on our pre-IND submission (see section: 1.12.1), a total of six BEMT dosage forms, representing high skin penetrating formulations, were assessed in the Photoallergenicity, Phototoxicity, Sensitization/Cumulative irritation and pivotal MUsT studies conducted under IND No. 146892. These dosage forms are not intended to be marketed; rather, they are "market image" formulations that represent common BEMT products identified in our market survey and are solely for use in the proposed clinical studies.

As part of our quality program, we ensured that the dosage forms evaluated were not adulterated and were appropriate for human use as indicated during the IND for the proposed studies. Additionally, our development program for the drug substance included the establishment of a new updated USP monograph for Bemotrizinol. Below is a quality overall summary for the drug substance and dosage forms tested.

Proprietary Name of Drug Substance: PARSOL® Shield

Non-Proprietary Dosage Forms to be tested:

- BEMT, PARSOL Shield, 6 %, with suitable solubilizers, Formulation SU-E-101413-85: Sunscreen oil with 10 % alcohol as penetration enhancer;
- BEMT, PARSOL Shield, 6 %, with suitable solubilizers; Formulation SU-E-101413-87: oil-in-water (O/W) emulsion;
- BEMT, PARSOL Shield, 6 %, with suitable solubilizers, Formulation SU-E-101413-89: water-in-oil (W/O) cream emulsion;
- Formulation SU-E-101413-91: Sunscreen oil vehicle with 10 % alcohol as penetration enhancer;
- BEMT, PARSOL Shield, 6 %, Formulation SU-E-101413-82: Petrolatum; and
- Formulation SU-E-101413-83: Petrolatum vehicle

Non-Proprietary Name of Drug Substance: Bemotrizinol (BEMT)

Company Name: DSM Nutritional Products, LLC

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Dosage Forms:	Topical sunscreen oil, oil-in-water (O/W) emulsion, water-in-oil (W/O) cream emulsion and Petrolatum formulation.
Strength(s):	6 % (w/w active)
Route of Administration:	Topical. For external use only.
Proposed Indication(s):	Helps prevent sunburn and appropriate indications under 21 CFR 352.