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PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	4 Feb 2022
TO:	Gladys Osis
PROTOCOL:	DSM Nutritional Products AG - DSM PT 2020 / CRLNJ2020-0494, Evaluation of Topically Applied Bemotrizinol for Human Phototoxic Potential (Pro00060762)
APPROVAL DATE:	4 Feb 2022
EXPIRATION DATE:	4 Feb 2023

IRB APPROVED DOCUMENTATION:

Protocol Version(s):

- Protocol Version 1 (Dated 17 December 2021)

Consent Form(s):

- Informed Consent Form (Advarra IRB Approved Version 4 Feb 2022)

Product Information:

- Solar Simulator Operational Instructions Using DCS-1 (Version 2, Dated 08/27/2021)
- Solar Simulator Operational Instructions Using DCS-2 (Version 2, Dated 08/27/2021)
- Ingredient List for Formula SU E 101413 85 (with 6% Parsol® SHIELD) and SU E 101423 91 (Placebo): Sunscreen oil with penetration enhancer (Not Dated)
- Ingredient List for Formulations with Petrolatum: SU E 101413 82 (with 6% Parsol® SHIELD) and SU E 101413 83 (placebo) (Not Dated)

The IRB approved the above referenced protocol and your site with the modifications listed below on 4 Feb 2022:

- **Modifications to the Informed Consent Form**

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Approved investigators and sites are required to submit to Advarra for review, and await a response, prior to implementing any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.