

ESG

RESPONSE TO PREA NON-COMPLIANCE LETTER

Jill Lindstrom, M.D., Director
Office of Immunology and Inflammation (OII)
Division of Dermatology and Dentistry (DDD)
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

**RE: NDA 209354 DUOBRII[®] (halobetasol propionate and tazarotene) Lotion,
0.01%/0.045%
Sequence 0071 – Response to PREA NON-Compliance Letter**

Dear Dr. Lindstrom,

Reference is made to NDA 209354 for Duobrii[®] (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045% originally approved April 25, 2019.

Reference is also made to the deferred pediatric study communicated as required post-marketing study with the approval of DUOBRII NDA 209354. Additional reference is made to the Deferral Extension Request filed on October 25, 2022 (Sequence 0055). Further reference is made to the FDA Notification of Non-Compliance with PREA letter dated April 7, 2025.

The purpose of this submission is to provide a formal response to the above referenced PREA Non-compliance letter. The response, which includes the reason(s) for delayed pediatric assessment and request for a deferral extension, can be found in section 1.17.2 of this submission.

This submission is provided in electronic Common Technical Document (eCTD) format and is approximately 8 MB in size. The content of the submission has been verified to be free of viruses using the latest version of Carbon Black Defense. The submission is being provided via the FDA's Electronic Submission Gateway (ESG). Please note that a letter of non-repudiation dated November 16, 2022, is on file with the Agency.

The material and data contained in this NDA submission are confidential. The legal protection of such confidential material is hereby claimed under the applicable provision of 18 USC, Section 331(j), and/or 21 CFR 314.430.

Should you have questions or comments regarding this submission, please do not hesitate to contact me.

Sincerely,

Carla.Sanders Digitally signed by Carla.Sanders
Date: 2025.05.13 07:24:18 -04'00'

BAUSCH Health

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