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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 0079 – 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 Agency Deferral Extension Granted communication dated October 24, 2025, with Agency advice to terminate the ongoing trial and submit the data collected to date in Cohort 1, which represents pediatric subjects 12 to less than 17 years of age. Further reference is made to Deferral Extension Granted communication dated January 13, 2026, acknowledging and agreeing with our deferral extension request and revised milestone of April 2026 due to additional time required to prepare and submit final data collected to date. Final reference is made to Notification of NON-Compliance with PREA dated June 12, 2026, due to Sponsor failing to meet postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) because we have not yet submitted our pediatric assessment for the following PMR:

PMR 3611-1, which was deferred until April 30, 2026.

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 a date by which we expect to submit the assessment, 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,

Please refer to e-signature page

BAUSCH Health

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| Approval Task Task<br>Verdict: Approved | Carla Sanders<br>Regulatory<br>21-Jul-2026 16:57:00 GMT+0000 |

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