



NDA 209354

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Bausch Health Americas, Inc.
Attention: Carla Sanders
Senior Manager, Global Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Carla Sanders:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Duobril (halobetasol propionate and tazarotene) lotion, which was approved on April 25, 2019.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for the following PMR:

PMR 3611-1, which was deferred until December 31, 2024.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a **"DEFERRAL EXTENSION REQUESTED"** in your response.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at <https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a **"RESPONSE TO PREA NON-COMPLIANCE LETTER."** To facilitate our review, submit this information to your NDA with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, contact Strother Dixon, Senior Regulatory Project Manager, at Strother.Dixon@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TATIANA OUSSOVA
04/07/2025 10:49:00 AM