

NDA 216227

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Harrow Eye, LLC
Attention: Carrie Underhill
Director of Regulatory Affairs
1A Burton Hills Boulevard, Suite 200
Nashville, TN 37215

Dear Carrie Underhill:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for IHEEZO (chloroprocaine hydrochloride ophthalmic gel) 3%, which was approved on September 27, 2022.

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 this PMR.

PMR 4352-1, which was deferred until December 31, 2025.

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, call Crystal Bland, MSHA, Regulatory Project Manager, at 301-837-7672 or email crystal.bland@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

William M. Boyd, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
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/

WILLIAM M BOYD
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