

NDA 203826

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Hikma Pharmaceuticals USA, Inc.
2 Esterbrook Lane
Cherry Hill, NJ 08003

Attention: Angela Zimarowski
Senior Regulatory Affairs Associate, Regulatory Affairs

Dear Angela Zimarowski:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Phenylephrine Hydrochloride injection, which was approved on December 20, 2012.

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 1991-1: 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 Lori Anne Wachter, Regulatory Project Manager, at (301) 796-3975 or Lori.Wachter@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology and
Nephrology
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/

MARY R SOUTHWORTH
04/03/2025 11:53:18 AM