



NDA 215309

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Incyte Corp
Attention: Fiona Lee
Director, Global Regulatory Affairs
1801 Augustine Cut-Off
Wilmington, DE 19803

Dear Fiona Lee:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Opzelura (ruxolitinib) cream, which was approved on September 21, 2021.

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

PMR 4147-1, which was due by February 29, 2024
PMR 4147-2, which was due by December 31, 2023

Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

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. We note that you requested a deferral extension on March 14, 2024; however, we have determined that your request was not submitted at least 90 days prior to the deferral expiration.

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 Sascha Randolph, Regulatory Project Manager, at Sascha.Randolph@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
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