NDA 21345/S-004
NDA 21345/S-005

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Mylan Ireland Limited
c/o Mylan Pharmaceuticals, Inc.
Attention: Amy Lynn Martin
Senior Director, Regulatory Affairs
3711 Collins Ferry Road
Morgantown, WV 26505

Dear Ms. Martin:

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Arixtra (fondaparinux sodium injection), which were approved on May 28, 2004.

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 PMRs 2151-1 and 2151-2, which were deferred until December 30, 2022.

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 December 14, 2022; however, we have determined that your request did not qualify for an extension/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 sNDA 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 Carleveva Thompson, Regulatory Project Manager, at 301-796-1403.

Sincerely,

{See appended electronic signature page}

Ann Farrell, MD
Director
Division of Nonmalignant Hematology
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/

ANN T FARRELL
02/28/2023 03:55:48 PM