NDA 021345/S-004
NDA 021345/S-005

NOTIFICATION OF NON-COMPLIANCE WITH PREA

Mylan Ireland Limited
c/o Mylan Pharmaceuticals Inc.
Attention: Martina O'Sullivan
Head of Global RA Injectables
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Ms. O'Sullivan:

Please refer to your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Arixtra (fondaparinux sodium injection) solution, 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 15, 2019. 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. 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

sNDAs 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 Charlene Wheeler, Senior Regulatory Health Project Manager, at (301) 796-1141.

Sincerely,

{See appended electronic signature page}

Rosanna Setse
(Acting) Deputy Director for Safety
Division of Non-Malignant 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/

ROSANNA W SETSE
04/27/2020 05:00:55 PM