DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203214/S-013

SUPPLEMENT APPROVAL
RELEASE FROM REMS REQUIREMENT

P F Prism C.V.
c/o Pfizer Inc.
500 Arcola Road
Collegeville, PA 19426

Attention: Alicia Holsey, M.S., RAC
Senior Manager, Worldwide Safety and Regulatory

Dear Ms. Holsey:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 20, 2016, submitted under section 505(b) for Xeljanz (tofacitinib) Tablets, 5 mg.

We also refer to our REMS Modification Notification letter dated January 13, 2016, and we acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated November 6, 2015.

This prior approval supplemental application provides for proposed modification to the approved REMS and proposes to eliminate the requirement for the approved REMS for Xeljanz (tofacitinib).

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Xeljanz (tofacitinib) Tablets was originally approved on November 6, 2012,

and the most recent REMS modification was approved on June 19, 2015. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

Your proposed modifications consist of elimination of the communication plan, and therefore, release from the requirement for a REMS for Xeljanz (tofacinib).

As communicated in the January 13, 2016 REMS Modification Notification Letter, we determined a communication plan is no longer necessary to include as an element of the approved REMS because the communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goals.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Xeljanz (tofacitinib).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Carol F. Hill, Senior Regulatory Health Project Manager for Safety, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

SALLY M SEYMOUR
02/08/2016