DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203214/S-006

SUPPLEMENT APPROVAL
REMS MODIFICATION APPROVAL

PF PRISM C.V.
c/o Pfizer, Inc.
445 Eastern Point Road
Groton, CT 06340

Attention: Nickie V. Kilgore, D.V.M.
Director, Worldwide Regulatory Strategy

Dear Dr. Kilgore:

Please refer to your Supplemental New Drug Application (sNDA) dated September 27, 2013, received September 27, 2013, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xeljanz (tofacitinib) and your risk evaluation and mitigation strategy (REMS) assessment dated September 27, 2013.

This Prior Approval supplemental new drug application provides for proposed modifications to the approved REMS and all other relevant REMS materials to reflect the change in NDA ownership, including revisions to indicate the new applicant name, address, and contact information.

We have completed our review of this supplemental application, as amended. 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) was originally approved on November 6, 2012. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of revisions to the

REMS document and all other relevant REMS materials to reflect the change in NDA ownership, including revisions to indicate the new applicant name, address, and contact information.

The timetable for submission of assessments of the REMS will remain the same as that approved on November 6, 2012.

There are no changes to the REMS assessment plan described in our November 6, 2012, letter.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 203214 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

Prominently identify the submission containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

NDA 203214 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 203214
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 203214

REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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 Philantha Bowen, Senior Regulatory Project Management Officere, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II

ENCLOSURE:
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
11/08/2013