DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203341/S-007
NDA 203341/S-008

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

PF PRISM C.V.
c/o Pfizer Inc.
Attention: Jay B. Nair, PhD
Global Regulatory Lead, Worldwide Safety and Regulatory
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Nair:

Please refer to your Supplemental New Drug Applications (sNDA) dated June 28, 2016 to Supplement 007, received June 28, 2016, and December 15, 2016 to Supplement 008, received December 15, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BOSULIF® (bosutinib) tablets, 100 and 500 mg.

The Prior Approval Supplement 007 provides for updates to the US Prescribing Information (USPI) Dosage and Administration section to include new dosing regimen. In addition, updates to the USPI Clinical Studies section related to the final study report and fulfillment of postmarketing commitment 1912-2: Continue follow-up of patients (on treatment and in protocol defined posttreatment follow-up) enrolled in Study 200-WW.

The Prior Approval Supplement 008 provides for updates to the USPI Adverse Reactions Postmarketing Experience section with the addition of Stevens Johnson's syndrome information.

APPROVAL & LABELING

We have completed our review of these supplemental applications., as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, and text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled *"SPL Standard for Content of Labeling Technical Qs and As*" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated June 28, 2016, containing the final report for the following postmarketing commitment listed in the September 4, 2012 approval letter.

PMC 1912-2 Continue follow-up of patients (on treatment and in protocol defined posttreatment follow-up) enrolled in Study 200-WW at least an additional 2 years past the March 28, 2011 cut-off date. Submit the Final Report, which will consist of an updated report containing, at a minimum, data through March 28, 2013.

Final Report Submission: December 2015

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our September 4, 2012, letter.

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 Kimberly Scott, Regulatory Project Manager, at (240) 402-4560.

Sincerely,

{See appended electronic signature page}

Albert Deisseroth, MD, PhD
Supervisory Associate Division Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

ALBERT B DEISSEROTH
04/13/2017