DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202570/S-023

SUPPLEMENT APPROVAL

PF PRISM C.V.
Attention: J. Nicole Earnhardt, Ph.D., R.A.C.
Senior Manager, Worldwide Safety & Regulatory
Pfizer, Inc.
10646 Science Center Drive
San Diego, CA 92121

Dear Dr. Earnhardt:

Please refer to your Supplemental New Drug Application (sNDA) dated August 9, 2017, received August 9, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XALKORI (crizotinib) capsules, 200 mg and 250 mg.

We also refer to our approval letter dated February 7, 2018, which contained the following error: The XALKORI labeling for sNDA 202570-024 was appended to the sNDA 202570-023 Approval Letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 7, 2018, the date of the original approval letter.

This Prior Approval supplemental new drug application revises the Dosage and Administration, Use in Specific Populations and Clinical Pharmacology sections of the package insert to incorporate results from a clinical pharmacology hepatic impairment trial to fulfill postmarketing requirement 1789-8.

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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

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

We have received your submission dated July 26, 2017, containing the final report for the following postmarketing requirement listed in the August 26, 2011, approval letter for this application.

1789-8	Conduct a multiple dose trial to determine the appropriate crizotinib dose in patients with various degrees of hepatic impairment.

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

We remind you that there is postmarketing requirement listed in the September 14, 2015 approval letter that is still open.

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 Ingrid Fan, Regulatory Project Manager, at (301) 796-5053.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

JEFFERY L SUMMERS
02/07/2018