NDA 202324/S-014

CORRECTED SUPPLEMENT APPROVAL

PF PRISM C.V. represented by Pfizer Manufacturing Holdings LLC
Attention: Melissa McMahon, MS
Director, Pfizer Global Regulatory Affairs
10646 Science Center Drive
San Diego, CA 92121

Dear Ms. McMahon:

Please refer to your supplemental new drug application (sNDA) dated December 7, 2021, received December 7, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Inlyta (axitinib) tablets.

We also refer to the approval letter and label dated September 22, 2022 that was subsequently mailed to you, which contained the following errors:

- The approval letter referenced the provision: Addition of 'Section 2.5, Dose Modification for Diarrhea; however, this section was removed from the USPI, so it should not have been referenced in the letter. Instead, this information was added to Section 2.2.

- Bavencio was misspelled

- The dates in the Recent Major Changes section of the USPI showed place holders instead of actual dates.

This corrected action letter and label incorporates the corrections of the errors. The effective date will remain September 22, 2022; the date of the original letter.

This Prior Approval supplemental new drug application provides for:

- Replacement of text with tables in Section 2.2, Dose Modification Guidelines

- Addition of dose modification for diarrhea for Inlyta in combination with avelumab or pembrolizumab in Section 2.2.

- Addition of adverse event data in Section 6.1, Clinical Trial Experience

- Sections 2.4, Dose Modification for Hepatic Impairment, and

5.11, Hepatotoxicity, were updated to be consistent with the sections of the approved USPIs of Keytruda and Bavencio related to the combination use of these products with Inlyta

- Final OS analysis data for study KEYNOTE-426 in Section 14.1
- Inclusion of hepatotoxicity in Section 17, Patient Counseling Information
- Inclusion of high blood pressure in Patient Information

APPROVAL & LABELING

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

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's automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insertwith 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 the FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to the FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to the FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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

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[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, call Kim J. Robertson, Senior Regulatory Health Project Manager, at (301) 796-1441, or kim.robertson@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Daniel Suzman, MD
Supervisory Associate Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S): Content of Labeling
- Prescribing Information
- Patient Package Insert

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/

DANIEL L SUZMAN
09/29/2022 02:36:35 PM