NDA 213736/S-001

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING REQUIREMENTS

Incyte Corporation
Attention: Aaron Packman, MBA
Executive Director, Global Regulatory Affairs
1801 Augustine Cut-Off
Wilmington, DE 19803

Dear Mr. Packman:

Please refer to your supplemental new drug application submitted and received August 28, 2020, and your amendments dated October 9, 2020, February 3, and 9, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pemazyre (pemigatinib), tablets.

This Prior Approval supplemental new drug application provides for revisions to:

- SECTION 2 Dosage And Administration Subsections 2.5 Recommended Dosage for Severe Renal Impairment , 2.6 Recommended Dosage for Severe Hepatic Impairment,
- SECTION 5 Warnings And Precautions Subsection 5.2 Hyperphospatemia and Soft Tissue Mineralization
- SECTION 6 Adverse Reactions Subsection 6.1 Clinical Trials Experience
- Section 7 Drug Interactions Subsection 7.2 Effect of Other Drugs on PEMAZYRE
- SECTION 8 Use In Specific Populations Subsections 8.6 Renal Impairment, 8.7 Hepatic Impairment
- SECTION 12 Clinical Pharmacology Subsections 12.2 Pharmacodynamics, 12.3 Pharmacokinetics
- SECTION 17 Patient Counseling Information of the Full Prescribing Information (FPI) with corresponding changes to the Patient Package Insert (PPI).

In addition, Highlights of Prescribing Information was updated to reflect revisions made to the FPI and minor formatting edits were made throughout the FPI.

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 Food and Drug Administration (FDA) 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 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 *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 New Drug Application (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 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).

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.

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[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.

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

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated August 28, 2020, containing the final reports for the following postmarketing requirements listed in the April 17, 2020, approval letter.

3801-2 Submit the analysis and datasets with the final study report for an ongoing hepatic impairment clinical trial to evaluate the pharmacokinetics and safety of pemigatinib in patients with normal hepatic function and patients with hepatic impairment. Design and conduct the trial in accordance with the FDA Guidance for Industry titled, "*Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling."*

3801-3 Submit the analysis and datasets with the final study report for an ongoing renal impairment clinical trial to evaluate the pharmacokinetics and safety of pemigatinib in patients with normal renal function and patients with renal impairment. Design and conduct the trial in accordance with the FDA Guidance for Industry titled; "*Pharmacokinetics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling."*

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there is a postmarketing requirement listed in the April 17, 2020, approval letter that is still open.

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]

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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]

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 Haroon Vohra, Pharm.D., Regulatory Health Project Manager, at 240-402-4471.

Sincerely,

{See appended electronic signature page}

Abhilasha Nair, MD
Associate Director for Safety (Acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

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