CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213736Orig1s000

OTHER REVIEW(S)

Clinical Inspection Summary

Date	4/9/2020
From	Yang-Min (Max) Ning, M.D., Ph.D. Kassa Ayalew, M.D., M.P.H. Good Clinical Practice Assessment Branch (GCPAB) Division of Clinical Compliance Evaluation (DCCE) Office of Scientific Investigations (OSI)
To	Naomi Horiba, M.D. Martha Donoghue, M.D. Stacie Woods, RPM Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD)
NDA #	213736
Applicant	Incyte Corporation
Drug	Pemigatinib (PEMAZYRE™)
NME (Yes/No)	Yes
Therapeutic Classification	Kinase inhibitor
Proposed Indication	Treatment of cholangiocarcinoma with FGFR2 fusion or rearrangement
Consultation Date	October 28, 2019
Review Priority	Priority
Summary Goal Date	April 10, 2020
Action Goal Date	May 1, 2020
PDUFA Date	May 29, 2020

I. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

Clinical data from Cohort A of an ongoing Phase 2 trial (Study INCB54828-202) was submitted to the Agency in support of a New Drug Application (NDA) for pemigatinib for the above proposed indication. Three clinical investigators [Dr. Raed Al-Rajabi (Site 018), Dr. David Gallinson (Site 020), and Dr. Vailbhav Sahai (Site 012)] and the study sponsor Incyte Corporation were selected for clinical inspections.

The inspections found no objectionable regulatory violations. The evidence for central determination of subjects for Cohort A and reported tumor response data was verifiable with information and documents available at sponsor's site.

Based on the results of these inspections, the clinical data generated from the three investigator sites, submitted by the sponsor, appear to be reliable and supportive of this NDA and the proposed indication for pemigatinib.

II. BACKGROUND

Pemigatinib is a small molecule kinase inhibitor of fibroblast growth factor receptors (FGFR) 1, 2, and 3. The sponsor Incyte Corporation has investigated its safety and efficacy in malignancies under IND 138179 (INCB054828). For this NDA, the sponsor submitted clinical data from Cohort A of an ongoing Phase 2 trial (Study INCB54828-202) and proposed an indication for accelerated approval of pemigatinib for use in patients with previously treated, locally advanced or metastatic cholangiocarcinoma that tests positive for a FGFR2 fusion or rearrangement.

Study INCB54828-202 (NCT02924376) is titled "A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects with Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR Translocations Who Failed Previous Therapy". To be eligible for the study, subjects were required to have metastatic or surgically unresectable cholangiocarcinoma who had evidence of disease progression after at least one line of prior systemic therapy. In addition, Subjects were required to have their FGF/FGFR alteration status evaluated before study enrollment. Based on the testing results at study sites, subjects were to be assigned to one of the following three cohorts:

- Cohort A: FGFR2 rearrangements or fusions
- Cohort B: FGF/FGFR alterations other than FGFR2 rearrangements or fusions
- Cohort C (in the United States only): negative for FGF/FGFR alterations

For enrolled subjects, their tumor biopsy specimens were required to be submitted to the sponsor's specified central genomics laboratory (b) (4) for molecular identification of FGFR alterations using next generation sequencing. Results from the central laboratory were to be used for final determination of cohort assignments for planned analyses. Note that Cohort A is the basis for the current application. The primary endpoint was the confirmed objective response rate (ORR) as assessed by an independent review committee (IRC).

Study subjects were scheduled to receive study treatment with INCB054828 or pemigatinib at a dose of 13.5 mg once daily on a 2-week-on and 1-week-off schedule (a cycle of every 21 days). Study treatment continued until disease progression, unacceptable toxicity, withdrawal of consent, or meeting other criteria for discontinuation as specified in the study protocol. Tumor response assessments were to be performed with CT/MRI scans every 2 cycles (± 3 days) for the first 2 assessments and thereafter every 3 cycles (± 3 days) until disease progression. All on-study scans, including baseline scans, were required to be submitted to the sponsor's contracted IRC (b) (4) for central review.

From 01/17/2017 through 03/22/2019 (data cutoff date for the interim analysis in this

NDA), this study enrolled 146 subjects, with 107 allocated to Cohort A based on the central genomics testing results. Sixty-one percent of subjects were from 34 study sites in the U.S. and 39% from 33 study sites in 11 countries and region across Western Europe and Asia.

For clinical inspections, the review division DO2 and OSI selected three clinical investigator, Dr. Raed Al-Rajabi (Site 018), Dr. David Gallinson (Site 020), Dr. Vailbhav Sahai (Site 012), and the study sponsor Incyte Corporation, with a primary focus on Cohort A. Relative to other domestic sites, these three sites had a high number of subjects enrolled. Sites 018 and 020 were also associated with a higher response rate of 50-75% in Cohort A than the reported overall response rate of 36% for this cohort. None of the three selected investigators had a history of FDA inspections prior to this application. Given this new molecular entity application, the sponsor inspection was requested to evaluate the overall conduct of this study and sponsor's determination of subjects for Cohort A for the reported efficacy analysis. Incyte Corporation had several FDA inspections, with the most recent one conducted in November 2018. The final compliance classification for each inspection was No Action Indicated.

III. RESULTS

1. **Raed Al-Rajabi, M.D. (Site 018)**
   2330 Shawnee Mission Parkway
   Mailstop 5003
   Westwood, KS 66205

   Dr. Al-Rajabi was inspected from January 27 through February 7, 2020, as a data audit for Study INCB54828-202. This was the initial FDA inspection of the investigator. The investigator site screened 10 subjects and enrolled 7 into the study, with two subjects to Cohort A and five to Cohort C. As of the data cutoff, one subject (Subject (b) (6)) in Cohort A remained on treatment and the other subject (Subject (b) (6)) in Cohort A was discontinued from study treatment due to disease progression; all 5 subjects in Cohort C were discontinued from study treatment due to disease progression or adverse event.

   All enrolled subjects' source records were reviewed during the inspection and were compared with the sponsor's submitted data listings for this site. The reviewed source records included but were not limited to the informed consent forms (ICF), cohort assignments, eligibility criteria, response assessments, adverse events (AEs), treatment discontinuation, concomitant medicines, and electronic case report forms (CRFs). Study-required regulatory documents and processes at the site were also reviewed, including the Institutional Review Board (IRB) approvals of the study protocol and informed consent and related correspondence, financial disclosures, study monitoring log and communications with the sponsor, reports to sponsor (e.g., electronic data capturing and reporting), protocol deviations, study drug accountability, and retention of study records.

The inspection revealed no regulatory deficiencies. There were no noticeable discrepancies identified between the reviewed source records and the submitted data listings. The primary efficacy measure was verifiable with the tumor assessment forms at the site. All serious adverse events were captured and reported. There was no observation of underreporting of adverse events from the site.

At the conclusion of this inspection, no Form FDA 483 was issued to the investigator.

2. David Gallinson, D.O. (Site 020)
150 Park Ave., 3rd Floor
Florham Park, NJ 07932-1049

Dr. Gallinson was inspected on December 16-18, 2019, as a data audit for Study INCB54828-202. This was the first FDA inspection of this investigator. The investigator site screened 9 subjects and enrolled 4 in Cohort A of the study. As of the date cutoff date (3/22/2019), one subject (Subject (b) (6)) remained on study treatment, three subjects were discontinued from study treatment due to disease progression (Subjects (b) (6) (b) (6)) or adverse event (Subject (b) (6)). At the time of the inspection, Subject (b) (6) was found to have discontinued study treatment due to disease progression and the last dose was on (b) (6).

Source records for all subjects were audited for the informed consent and process, eligibility criteria, enrollment logs, FGFR test reports, tumor specimens' submissions, scans performed and assessments, laboratory tests, and case report forms. Documents related to the conduct of this study at the site were also reviewed, including the study protocol/amendments and IRB's approvals, financial disclosures, site training records, study monitoring and reporting, test article accountability, and overall protocol compliance.

The inspection found consistency between the submitted data listings and the reviewed source records, with no significant deficiencies identified. Regarding the missed QTcF values in the electrocardiogram data listings, the inspection found that the site had QTcB values, which were reviewed and reported to be within the required range. No underreporting of adverse events and protocol violations was identified.

No Form FDA 483, Inspectional Observations, was issued at the closeout of the inspection. There was one discussion item which related to no clear record for three bottles of test article that might have been destryed on-site following the previous institutional procedures for drug destruction. The investigator acknowledged the finding and committed to ensuring accurate and complete drug accountability records in the future.

3. Vailbhav Sahai, M.D., M.S. (Site 012)
2800 Plymouth Rd, 300 Main Rm 325
Ann Arbor, MI 48109-5000

Dr. Sahai was inspected from January 13 through January 21, 2020, as a data audit for Study INCB54828-202. This was the first FDA clinical inspection for the investigator. The site screened 11 subjects and enrolled 8 into the study, with six subjects in Cohort A (Subjects (b) (6)), one subject in Cohort B (Subject (b) (6)), and one in Other (Subject (b) (6), a protocol waived subject acknowledged by the local IRB who was found to have had inadequate tumor specimens for testing of FGFR alterations per the central laboratory report). Of note, Subject (b) (6) who was initially assigned to Cohort B was reassigned to Cohort A based on the central laboratory testing result (see additional information below in the Sponsor Inspection). As of the data cutoff date, all enrolled subjects, including those in Cohort A, were discontinued from study treatment due to disease progression. Of note, Subject (b) (6) was initially assigned to Cohort B but reassigned to Cohort A based on the central laboratory testing result (see additional information below in the sponsor inspection)

Source records for all subjects were reviewed and compared with the submitted data listings for the site. The reviewed records included but were not limited to the informed consent, inclusion/exclusion, FGFR gene alteration status, radiographic scans and assessment documentation, laboratory tests, adverse events, concomitant medications, test article dosing and accountability. Site's documents related to the conduct and oversight of this study were also examined, including the study the IRB's approvals of the protocol and ICFs, IRB's continuing reviews, signed FDA 1572s, Delegation and Signature logs, staff training records, site monitoring reports and correspondence, data capture system and procedures, and study records' retention.

The inspection found no significant regulatory deficiencies. The submitted data listings were verifiable with source records at the site. There was no evidence of under-reporting of adverse events.

No Form FDA 483 was issued to the investigator at the close of this inspection. Discussion items with the investigator and study team included: 1) the protocol waiver (for Subject (b) (6)) was not communicated to the sponsor in a timely manner despite the IRB's acknowledgement of the investigator's request for the subject; 2) incomplete source documentation noted for Subject (b) (6). The study chart for this subject did not contain the drug diary documenting information related to the completion of the Cycle 1 Visit. The investigation of this finding led to a Note to File that acknowledged the missing document was lost in transit from the clinic to the Oncology Clinical Trials Support Unit. The reported drug accountability for this cycle was based on the medical record note documented by the study coordinator.

Reviewer's Comments: *The cohort assignments of study subjects at this site were found to be consistent with the information contained in relevant documents collected from the sponsor inspection. The inclusion of the above-listed 6 subjects in Cohort A was supported by FGFR testing results from the central laboratory. The above discussion items at the closeout of the inspection represent inspectional findings, which to the reviewer's assessments, are not significant to impact the cohort assignment or place either study subject at risk.*

4. Incyte Corporation (Sponsor)
1801 Augustine Cut-Off
Wilmington, Delaware 19803

The sponsor inspection was performed on February 3-10, 2020 to evaluate the conduct and management of Study INCB54828-202. This was the fifth inspection of this sponsor in the last 8 years.

The inspection included a review of the sponsor's history, organizational reporting structure, standard operating procedures and records, contract research organizations (CRO) and vendors involved in the study and related work orders and agreements, data management plans and processes, registration of the study on ClinicalTrials.gov, key employees in the management of the study and their responsibilities, selection and monitoring of participating investigators and the signed agreements, financial disclosures, selection of monitors, protocol-required training, electronic systems used for data collection and handling, safety reporting, quality assurance and audits during the study, records archiving program and retention.

The inspection examined the sponsor's data management thoroughly for the study, with special focuses on the reported central determination of subjects for Cohort A per FGFR testing results from the sponsor's designated central laboratory, (b) (4), and data transfer to the sponsor from the CRO (b) (6) which performed IRC for the study.

The inspection revealed no objectionable regulatory violations, with no Form FDA 483 issued to the sponsor. For Cohort A, a total of 107 subjects were found to have documented evidence of FGFR2 rearrangements or fusions in tumor specimens based on the (b) (4) testing reports. Of note, two subjects (Subjects (b) (6) (b) (6)) who were originally assigned to Cohort A with the local (b) (4) laboratory reports were found to have inadequate tumor specimens per the (b) (4) reports and were consequently excluded from Cohort A due to the lack of FGFR alteration information. In addition, two subjects (Subjects (b) (6)) who were initially assigned to Cohort B were reassigned to Cohort A based on the (b) (4) testing results and subsequent discussions between (b) (4) and the sponsor. The two cohort-reassigned subjects showed "FGFR2 rearrangement (N/A Partner)" per the (b) (4) reports. The data transfer from the independent review CRO was carried

out on April 11, 2019 (with the data cutoff date of March 22, 2019) according to the agreed Imaging SDTM Data Transfer Plan. Examination of the raw data received by the sponsor in a few randomly selected subjects found that the raw data were consistent with those found in the sponsor's submitted datasets to this NDA. Examination of the eCRF data for 6 randomly selected subjects found consistency with the submitted data in the reported FGFR2 status, scans performed, adverse events, and dose modifications.

Overall, the inspectional findings indicated that the sponsor had proper management and adequate oversight of Study INCB54828-202. Based on the findings and collected documents, the sponsor's submitted data for this study appear reliable.

{See appended electronic signature page}

Yang-Min (Max) Ning, M.D., Ph.D.
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

CONCURRENCE: *{See appended electronic signature page}*

Kassa Ayalew, M.D., M.P.H
Branch Chief
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

cc:

Central Doc. Rm. NDA 213736 for pemigatinib
Review Division /Division Director/S Lemery
Review Division /Medical Team Leader/M Donoghue
Review Division /Medical Officer/N Horiba
Review Division/Project Manager/S Woods
OSI/Office Director/D Burrow
OSI/DCCE/ Division Director/N Khin
OSI/DCCE/GCP Branch Chief/K Ayalew
OSI/DCCE/GCP Acting Lead/YM Ning
OSI/ GCP Program Analysts/ Joseph Peacock/Yolanda Patague
OSI/Database PM/Dana Walters

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/s/

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	March 3, 2020
To:	Stacie Woods, PharmD Regulatory Project Manager **Division of Oncology Products 2 (DOP2)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Sharon R. Mills, BSN, RN, CCRP Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Emily Dvorsky, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	PEMAZYRE (pemigatinib)
Dosage Form and Route:	tablets, for oral use
Application Type/Number:	NDA 0213736
Applicant:	Incyte Corporation

1 INTRODUCTION

On September 30, 2019, Incyte Corporation submitted for the Agency's review an original New Drug Application (NDA) 0213736 for PEMAZYRE (pemigatinib) tablets. The proposed indication for PEMAZYRE (pemigatinib) tablets is for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Oncology 3 (DO 3) on October 10, 2019, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for PEMAZYRE (pemigatinib) tablets.

2 MATERIAL REVIEWED

- Draft PEMAZYRE (pemigatinib) tablets PPI received on September 30, 2019, and received by DMPP on February 21, 2020.
- Draft PEMAZYRE (pemigatinib) tablets Prescribing Information (PI) received on December 20, 2019, revised by the Review Division throughout the review cycle, and received by DMPP on February 21, 2020.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the PPI the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The PPI is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the PPI is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI.

Please let us know if you have any questions.

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FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: March 2, 2020

To: Naomi Horiba, M.D., Medical Officer
Leigh Marcus, M.D., Medical Officer
Division of Oncology 3 (DO 3)

Stacie Woods, PharmD, Regulatory Project Manager

From: Emily Dvorsky, PharmD, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Susannah O'Donnell, MPH, RAC, Team Leader, OPDP

Subject: OPDP Labeling Comments for PEMAZYRE (pemigatinib) tablets, for oral use

NDA: 213736

In response to DO 3's consult request dated October 10, 2019, OPDP has reviewed the proposed product labeling (PI), patient package insert (PPI), and carton and container labeling for the original NDA submission for PEMAZYRE (pemigatinib) tablets, for oral use.

PI and PPI: OPDP's comments on the proposed labeling are based on the draft PI received by electronic mail from DO 3 (Stacie Woods) on February 21, 2020, and are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review will be completed, and comments on the proposed PPI will be sent under separate cover.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling submitted by the Sponsor to the electronic document room on February 14, 2020, and we do not have any comments.

Thank you for your consult. If you have any questions, please contact Emily Dvorsky at (240)402-4256 or Emily.Dvorsky@fda.hhs.gov.

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EMILY M DVORSKY
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MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	February 20, 2020
Requesting Office or Division:	Division of Oncology 3 (DO3)
Application Type and Number:	NDA 213736
Product Name and Strength:	Pemazyre (pemigatinib) Tablets, 4.5 mg, 9 mg and 13.5 mg
Applicant/Sponsor Name:	Incyte Corporation
OSE RCM #:	2019-2010-1
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container labels received on February 14, 2020 for Pemazyre. Division of Oncology 3 (DO3) requested that we review the revised container labels for Pemazyre (Appendix A) to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The Applicant implemented all of our recommendations and we have no additional recommendations at this time.

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[a] Stewart J. Label and Labeling Review for Pemazyre (NDA 213736). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 FEB 06. RCM No.: 2019-2010.

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LABLE AND LABELING REVIEW
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	February 6, 2020
Requesting Office or Division:	Division of Oncology 3 (DO3)
Application Type and Number:	NDA 213736
Product Name, Dosage Form, and Strength:	Pemazyre (pemigatinib) Tablets, 4.5 mg, 9 mg and 13.5 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Incyte Corporation
FDA Received Date:	September 30, 2019 and December 20, 2019
OSE RCM #:	2019-2010
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

Reference ID: 4557819

1 REASON FOR REVIEW

As a part of the NDA review process, this review responds to the Division of Oncology 3 consult for DMEPA to review the proposed Pemazyre prescribing information (PI) and container labels for areas of vulnerability that may lead to medication errors.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Label and Labeling Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B – N/A
Human Factors Study	C – N/A
ISMP Newsletters*	D – N/A
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F – N/A
Labels and Labeling	G

N/A=not applicable for this review
*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We performed a risk assessment of the proposed container labels, and PI for Pemazyre (pemigatinib) to identify deficiencies that may lead to medication errors and other areas of improvement. We identified areas of the container labels that can be modified to support the safe use of this product.

4 CONCLUSION & RECOMMENDATIONS

Our evaluation of the proposed PI did not identify areas of vulnerability that may lead to medication errors. However, the proposed container labels can be improved to increase clarity, readability, and the prominence of important information to promote the safe use of the product. We provide recommendations for Incyte in Section 4.2 below.

4.1 RECOMMENDATIONS FOR INCYTE CORPORATION

We recommend the following be implemented prior to approval of this NDA:

A. Container Labels

Reference ID: 4557819

1. To ensure consistency with the Prescribing Information, revise the statement, [redacted]^(b) (4) to read "Recommended Dosage: See prescribing information."

2. Ensure the barcode is surrounded by sufficient white space to allow scanners to correctly read the barcode in accordance with 21 CFR 201.25(c)(i).

3. Ensure that there are no other numbers located in close proximity to the expiration date where it can be mistaken as the expiration date.

4. As currently presented, the product codes in the NDC numbers (middle 3 digits) are sequential (e.g., 026, 027 and 028). The middle digits are traditionally used by healthcare providers to check the correct product, strength, and formulation. The similarity of the product code numbers has led to selecting and dispensing of the wrong strength and wrong drug. Therefore, assignment of sequential numbers for the middle digits is not an effective differentiating feature. Revise the product code in the NDC numbers to ensure that the middle 3 digits (XXX) are not sequential between the strengths.
    a. If for some reason the middle digits cannot be revised, increase the prominence of the middle digits by increasing their size in comparison to the remaining digits in the NDC number or put them in bold type. For example: XXXXX-XXX-XX.

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Pemazyre received on December 20, 2019 from Incyte Corporation.

Table 2. Relevant Product Information for Pemazyre	
Initial Approval Date	N/A
Active Ingredient	pemigatinib
Indication	For the treatment of adults with previously treated, locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement as detected by an FDA-approved test.
Route of Administration	Oral
Dosage Form	Tablets
Strength	4.5 mg, 9 mg and 13.5 mg
Dose and Frequency	Recommended dose is 13.5 mg orally once daily for 14 days followed by 7 days off therapy. Continue treatment until disease progression or unacceptable toxicity occurs.
How Supplied	Bottles of 14 tablets with child-resistant closure
Storage	Room temperature 20 - 25°C (68 - 77°F); excursions permitted to 15 - 30°C (59 - 86°F).
Container Closure	(b) (4) HDPE bottle with a (b) (4) (b) (4) child resistant closure, including a (b) (4) cap and a (b) (4) (b) (4) closure.

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[a] along with postmarket medication error data, we reviewed the following Pemazyre labels and labeling submitted by Incyte Corporation.

- Container label received on September 30, 2019
- Carton labeling received on September 30, 2019
- Prescribing Information (Image not shown) received on December 20, 2019, available from \\cdsesub1\evsprod\nda213736\0019\m1\us\draft-labeling-text-clean.docx

G.2 Label and Labeling Images

(b) (4)

[a] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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