ND A219552

ANDA TENTATIVE APPROVAL

Sandoz Inc.
ttention: Gregory Seitz
Head U.S. Regulatory ffairs Generics

Dear Gregory Seitz:

This letter is in reference to your abbreviated new drug application (ND A) received for review on pril 17, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Pemigatinib Tablets, 4.5 mg, 9 mg, and 13.5 mg.

We have completed the review of this ND Aand have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C ct. We have determined your Pemigatinib Tablets, 4.5 mg, 9 mg, and 13.5 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Pemazyre Tablets 4.5 mg, 9 mg and 13.5 mg, of Incyte Corporation (Incyte) ND A- 213736.

However, we are unable to grant final approval to your ND Aat this time because of the patent issue noted below. Therefore, the ND Ais **tentatively approved**. This determination is based upon information available to the gency at this time (e.g., information in your ND Aand the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C ct.

The RLD upon which you have based your ND A, Incyte's Pemazyre Tablets 4.5 mg, 9 mg and 13.5 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
9,611,267 (the '267 patent)	January 30, 2035
10,131,667 (the '667 patent)	pril 17, 2034
11,466,004 (the '004 patent)	May 3, 2039

11,628,162 (the '162 patent)	August 30, 2040
12,552,792 (the '792 patent)	October 3, 2040

With respect to the '267 and '667 patents, your ANDA contains paragraph III certifications to each of the patents under section 505(j)(2)(A)(vii)(III) of the FD&C Act stating that Sandoz Inc. (Sandoz) will not market Vonjo Tablets, 4.5 mg, 9 mg, and 13.5 mg prior to the expiration of the patents. Therefore, final approval of your ANDA may not be granted pursuant to section 505(j)(5)(B)(ii) of the FD&C Act until the '267 patent has expired, currently January 30, 2035.

Your ANDA contains paragraph IV certifications to the '162 and '792 patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Vonjo Tablets, 4.5 mg, 9 mg, and 13.5 mg, under this ANDA. You have notified the Agency that Sandoz complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and the two action for infringement of the '162 patent was brought against Sandoz within the statutory 45-day period.

With respect to the '004 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this is a method-of-use patent that does not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for the listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, if your ANDA receives final approval, it may be subject to certain requirements and recommendations post approval, including requirements for labeling and promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/about-new-drug-application-nda-and-requirements-resources-approved-nda.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains new data, information, or other changes to the ANDA may require a period of 3 months for Agency review. Accordingly, such request for final approval should be

submitted no later than months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available guidance for industry related to amendments under the Generic Drug User Fee Program to determine the duration of Agency review and need to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of court decision, settlement or licensing agreement, or other information described in 21 CFR 14.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted via one of these channels and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requesting bove, the Agency may request, at any time prior to the date of final approval, that you submit additional amendments containing information specified by the Agency. Failure to submit either or, if requested, both types of amendments described bove may result in delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act and will not be listed in the Orange Book.

ANDA 219552

For further information on the status of this ANDA or upon submitting amendment to the ANDA, please contact Dina Smith, PharmD, RPh, Regulatory Project Manager, at (301) 796 - 3652.

Sincerely yours,

{See appended electronic signature page}

For Kendra S. Stewart, R.Ph., PharmD.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Catherine l
e l

i ita y si ned by Catherine l e l
ate: 6/01/2026 07:22:39AM l
GUI : 5407887a000a1c0c26055eafb8e3258a l