From: Pam Politis <ppolitis@incyte.com>
Date: December 1, 2020 at 6:01:00 AM MST
To: "Showers, Aryan, DOH" <Aryan.Showers@state.nm.us>
Cc: Missy Banashak <mbanashak@incyte.com>
Subject: [EXT] Comments re: Proposed Section 804 Importation Plan (SIP)

Dear Director Showers,
Attached please find comments regarding the New Mexico proposed Wholesale Prescription Drug Importation Program. These comments are submitted pursuant to the Wholesale Prescription Drug Importation Act, 26-4-1 to 26-4-10 NMSA 1978 on behalf of Incyte Corporation to the New Mexico Department of Health. We appreciate the opportunity to submit comments, and welcome any questions you may have regarding the comment letter.
Thank you very much for your consideration.
Sincerely,
Pam Politis

Pamela Politis, JD, PhD
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December 1, 2020

Aryan Showers
Director, Office of Policy and Accountability
New Mexico Department of Health
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Santa Fe, NM 87505
Aryan.showers@state.nm.us
505-470-4141

Re: Delisting Jakafi and Jakavi on the Proposed Section 804 Importation Plan (SIP) and Wholesale Prescription Drug Importation Program

Dear Director Showers:

Incyte, a biopharmaceutical company that manufactures and markets Jakafi® (ruxolitinib tablets) in the United States, appreciates the opportunity to submit comments to the New Mexico Department of Health ("DOH") proposed Section 804 Importation Plan ("NM Proposed SIP") developed under the State's Whole Sale Prescription Drug Importation Program. As you know, the U.S. Food and Drug Administration ("FDA") published a Final Rule in the Federal Register on October 1, 2020, to allow the importation of "eligible prescription drugs" from Canada. *See* Importation of Prescription Drugs Final Rule, 85 Fed. Reg. 62095 (Oct. 1, 2020) ("Final Rule"). DOH has indicated that it intends to submit its SIP, including a list of prescription drugs for importation from Canada, to FDA for its approval by December 15, 2020.

The NM Proposed SIP lists a Canadian drug, Jakavi® (ruxolitinib tablets), for importation. *See* NM Proposed SIP at 57. As explained below, key differences between the FDA-approved NDA for Jakafi and the Canadian-approved application for Jakavi mean that the two drugs are not "eligible prescription drugs." Accordingly, they should be removed from the NM Proposed SIP before it is submitted to FDA.

Incyte is a biopharmaceutical company that focuses on the discovery, development, and commercialization of novel therapeutics to improve the lives of patients with cancer and other diseases. Incyte believes that investment in good science and the rigorous pursuit of research and development (R&D) excellence can translate into innovative medicines that can positively affect patients' lives. In addition to our marketed products, we have a broad and diversified selection of clinical candidates in our growing portfolio. We comment here on the incorrect inclusion of one of our products, Jakafi, in the NM Proposed SIP.

FDA's Final Rule defines "eligible prescription drug" as a drug that is approved by the Canadian Health Products and Food Branch (HFPB), and "but for the fact it deviates from the required U.S. labeling, also

meets the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently commercially marketed in the United States, including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities." Final Rule at 62126-27 (21 C.F.R. § 251.2). Accordingly, the critical question in determining whether Jakavi is an "eligible prescription drug" for importation is whether it meets the conditions of the FDA-approved NDA for Jakafi (other than labeling). This standard is not met here.

In 2009, Incyte licensed the ex-U.S. development and commercial rights for ruxolitinib to a different biopharmaceutical company, Novartis. *See* Press Release, Incyte Announced Major Collaboration and License Agreement for Two Hematology-Oncology Programs (Nov. 25, 2009), https://bit.ly/34YaXd6.

Since that time, the development, manufacturing, and marketing paths have diverged and led to important product differences between the drug product for the US market and the rest of world. Those differences persist today. As illustrated in the following chart, Jakafi and Jakavi are manufactured by different entities, have different approved indications, are sold in different dosage strengths, and have different physical appearances. *See also* NM Proposed SIP Appendix, https://bit.ly/2UMRDuA (including Jakafi label at 1619 and Jakavi drug monograph at 1659).

PRODUCT FEATURES	Jakafi® (ruxolitinib tablets)	Jakavi® (ruxolitinib tablets)
NDA/NDS #	NDA 202192	DIN # 02388006
Country/ Approval Date	U.S./Nov 2011	Canada/July 2012
Approved Indications	• intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults. • polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. • steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.	• the treatment of splenomegaly and/or its associated symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), postpolycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. • the control of hematocrit in adult patients with polycythemia vera (PV) resistant to or intolerant of a cytoreductive agent.
Applicant/ Manufacturer	Incyte Corporation	Novartis Pharmaceutical Canada Inc
How supplied	60 count bottles	HDPE bottles with child resistant closures (60 tablets) and in blister packaging (4x14 tablets).
Strengths	5, 10, 15, 20, 25 mg	5, 10, 15, 20 mg

Appearance	Round tablet with “INCY” on one side and “5”, “10” on the other; Oval tablet with “INCY” on one side and “15”, “25” on the other; Capsule shaped tablet with “INCY” on one side and “20” on the other	Round curved white to almost white tablets with “NVR” debossed on one side and “L5”, “L10” debossed on the other side; Ovaloid curved white to almost white tablet with “NVR” debossed on one side and “L15” debossed on the other side; Elongated curved white to almost white tablet with “NVR” debossed on one side and “L20” debossed on the other side.
Images of Tablet(s)		

As a result, Jakavi cannot meet the conditions in the Jakafi NDA "relating to the drug substance, drug product, production process, quality controls, equipment, and facilities," 21 C.F.R. § 251.2, and it is not an "eligible prescription drug."

This error in the NM Proposed SIP should be corrected now, before the SIP is submitted to FDA. As the NM Proposed SIP properly recognizes, it must comply with FDA's Final Rule, and exclude drugs that do not meet the definition of "eligible prescription drug." *See* NM Proposed SIP at 4, 11, and 32. Thus, for example, as DOH has recognized:

- "The program design *must ensure that only eligible prescription drugs meeting the FDA's requirements regarding safety and effectiveness are selected* and that the program demonstrates substantial savings for New Mexico consumers." *Id.* at 4 (emphasis added).
- "*Medications were excluded if they did not meet the federal definition of an eligible drug*." *Id.* at 11 (emphasis added).
- "Eligible prescription drug means a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act that has been approved and has received a Notice of Compliance and a Drug Identification Number (DIN) from the Health Products and Food Branch of Health Canada 2020-199 123 (HPFB) and, but for the fact that it deviates from the required U.S. labeling, also meets the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently commercially marketed in the United States, *including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities*." *Id.* at 32 (emphasis added).

Therefore, Incyte respectfully requests that the New Mexico Department of Health exclude Jakafi and Jakavi from its list of "eligible prescription drugs" for importation when it sends the SIP to FDA for authorization.[1]

Sincerely,

DocuSigned by:
Barry Flannelly
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Barry Flannelly

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EVP and GM Incyte US

[1] Given this fundamental, threshold reason why Jakavi is ineligible under FDA's Final Rule, these comments do not address the many other reasons why FDA's Final Rule does not withstand legal scrutiny or other legal issues with the NM Proposed SIP. Incyte does not waive any rights to such claims and reserves our right to pursue any and all such claims.