

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

212327Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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****

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| Date of This Review: | March 12, 2019 |
| Application Type and Number: | NDA 212327 |
| Product Name and Strength: | Inrebic (fedratinib) capsule, 100 mg |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Impact Biomedicines, Inc. (Impact) wholly owned subsidiary of Celgene Corporation (Celgene) |
| Panorama #: | 2019-28945730 |
| DMEPA Safety Evaluator: | Stephanie DeGraw, PharmD |
| DMEPA Team Leader: | Hina Mehta, PharmD |

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Inrebic, which was found conditionally acceptable under IND 78286 on January 2, 2019.^a We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Inrebic would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment for Inrebic.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The March 8, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Inrebic.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on March 8, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products (DHP) on March 8, 2019, they stated no additional concerns with the proposed proprietary name, Inrebic.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Inrebic, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-484.

3.1 COMMENTS TO IMPACT BIOMEDICINES, INC.

We have completed our review of the proposed proprietary name, Inrebic, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on January 29, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

^a Straka, M. Proprietary Name Review for Inrebic (IND 78286). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JAN 02. Panorama No.: 2018-24431499.

4 REFERENCE

- 1. USAN Stems** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

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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03/12/2019 12:23:11 PM

HINA S MEHTA
03/12/2019 12:42:07 PM

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