CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212018Orig1s000

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*****

Date of This Review:	October 18, 2018
Application Type and Number:	NDA 212018
Product Name and Strength:	Balversa (erdafitinib) tablets, 3 mg, 4 mg, and 5 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Janssen Biotech, Inc.
Panorama #:	2018-26101337
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader (Acting):	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Balversa, which was found conditionally acceptable under IND 117490 on December 19, 2017.[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 Balversa would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment for Balversa.

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 October 10, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name, Balversa.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on October 15, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 1 (DOP1) on October 18, 2018, they stated no additional concerns with the proposed proprietary name, Balversa.

3 CONCLUSIONS

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, Balversa, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO JANSSEN BIOTECH, INC.

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

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[a] Gao, T. Proprietary Name Review for Balversa (IND 117490). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 DEC 19. Panorama No.: 2017-16225876.

If any of the proposed product characteristics as stated in your submission, received on September 21, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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/

TINGTING N GAO
10/18/2018

SEVAN H KOLEJIAN
10/18/2018