CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215383Orig1s000

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:	March 11, 2021
Application Type and Number:	NDA 215383
Product Name and Strength:	Welireg (belzutifan) tablets, 40 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (Merck)
Panorama #:	2020-44423245
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Ashleigh Lowery, PharmD, BCCCP

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Welireg, which was found conditionally acceptable under IND 137354 on October 19, 2020.[a]

Merck submitted the name, Welireg, under NDA 215383 for review on December 18, 2020. We noted the proposed Welireg Prescribing Information[b] submitted to the NDA contains information for dose reductions for adverse reactions that were not included in the Request for Proprietary Name Review received on December 18, 2020. Thus, Merck submitted an Amendment to Request for Proprietary Name Review[c] on February 18, 2021 to include additional dose modifications for adverse reactions (See Table 1 below) in response to FDA's February 11, 2021 Information Request[d].

Table 1. Recommended Dose Modifications for Welireg

Adverse Reactions	Severity*	Dose Modification
Anemia (b) (4) *[see Warnings and Precautions (5.1)]*	(b) (4)	• Withhold until (b) (4) • Resume at a reduced dose (b) (4) or discontinue depending on the severity (b) (4) of anemia.
	(b) (4)	• Withhold until (b) (4) • Resume at a reduced dose (b) (4) or permanently discontinue (b) (4).
Hypoxia *[see Warnings and Precautions (5.2)]*	(b) (4)	• (b) (4) withhold until resolved (b) (4) • Resume at reduced dose (b) (4) (b) (4) depending on the severity (b) (4) of hypoxia.
	(b) (4)	• Withhold until resolved (b) (4) • Resume at reduced dose (b) (4) or discontinue depending on the severity (b) (4) of hypoxia.
	(b) (4)	• Permanently discontinue.

[a] Thomas, S. Proprietary Name Review for Welireg (IND 137354). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Oct 19. Panorama No.: 2020-41152092.

[b] Welireg [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. 2021 Jan 15. Available from \\CDSESUB1\evsprod\nda215383\0006\m1\us\01-crt-uspi-mk6482-t-original.doc.

[c] Amendment to Request for Proprietary Name Review. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. 2021 Feb 19. Available from: \\CDSESUB1\evsprod\nda215383\0009\m1\us\comments-advice-req-ind.pdf.

[d] Fahnbulleh, F. Information Request for NDA 215383 - belzutifan- Proposed PNR (Welireg). Silver Spring (MD): FDA, CDER, OSE (US); 2021 Feb 11.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Welireg would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Welireg.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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. We also evaluated previously identified names taking into account the additional dose reductions (40 mg and 80 mg). Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The January 15, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Welireg.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 1 (DO1) via e-mail on March 3, 2021. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 1 (DO1) on March 9, 2021, they stated no additional concerns with the proposed proprietary name, Welireg.

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, Welireg, 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 MERCK SHARP & DOHME CORP., A SUBSIDIARY OF MERCK & CO., INC.

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

If any of the proposed product characteristics as stated in your submission received on December 18, 2020 and amendment received on February 18, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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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