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APPLICATION NUMBER:

209606Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

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)

Date of This Memorandum: July 13, 2017
Requesting Office or Division: Division of Hematology Products (DHP)
Application Type and Number: NDA 209606
Product Name and Strength: Idhifa (enasidenib) Tablets
50 mg, 100 mg
Applicant/Sponsor Name: Celgene
Submission Date: June 06, 2017
OSE RCM #: 2017-17-1
DMEPA Primary Reviewer: Leeza Rahimi, Pharm.D.
DMEPA Team Leader: Hina Mehta, Pharm.D.

1 PURPOSE OF MEMO

Division of Hematology Products (DHP) requested that we review the revised container labels for Idhifa (enasidenib) Tablets (Appendix A) to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.^a Sponsor has accepted most of our previous recommendations for the container labels. However, we identified additional areas in the container labels that can be improved to increase the readability and clarity of information to promote the safe use of the product. We note that the net quantity statement is in close proximity of the statement for product strength. We provide letter-ready recommendations for the Applicant in Section 3 of this review.

2 CONCLUSION

DMEPA concludes that the container labels can be improved to increase the clarity of information to promote the safe use of the product. Please see recommendations for the Applicant in Section 3 below:

^a Rahimi, L. Label and Labeling Review for Idhifa (enasidenib) Tablets (NDA 209606). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 APR 07. RCM No.: 2017-17.

3 RECOMMENDATIONS FOR CELGENE

We recommend the following be implemented prior to approval of this NDA:

1. Relocate the net quantity statement away from the product strength, such as to the bottom of the principal display panel. From post-marketing experience, the risk of numerical confusion between the strength and the net quantity increases when the net quantity statement is located in close proximity to the strength statement.

APPENDIX A. LABEL AND LABELING SUBMITTED ON JUNE 6, 2017

Container labels



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/s/

LEEZA RAHIMI
07/13/2017

HINA S MEHTA
07/13/2017

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