CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209092Orig1s000

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:	November 21, 2016
Application Type and Number:	NDA 209092
Product Name and Strength:	Kisqali (ribociclib) tablets, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis
Panorama #:	2016-9896919-1
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Kisqali, based the change in dose. The proposed proprietary name, Kisqali, was found acceptable under NDA 209092 on September 27, 2016.[a] The dose of the product was originally presented as 600 mg/day and 400 mg/day in the Request for Proprietary Name Review submission submitted on August 29, 2016. However, in the proposed Prescribing Information submitted on August 29, 2016 and November 4, 2016, it states that Kisqali dose may be modified further to 200 mg/day for adverse events so the dose can be either 200 mg/day, 400 mg/day, or 600 mg/day.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in dose (the additional dose reduction to 200 mg per day for adverse events). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The November 21, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 is acceptable.

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

[a] Gao T. Proprietary Name Review for Kisqali (NDA 209092). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 Sept 27. Panorama No. 2016-9896919.

REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

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/s/

TINGTING N GAO
11/21/2016

CHI-MING TU
11/21/2016

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Date of This Review:	September 27, 2016
Application Type and Number:	NDA 209092
Product Name and Strength:	Kisqali (ribociclib) tablets, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis
Panorama #:	2016-9896919
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Kisqali, which was found conditionally acceptable under IND 117796 on April 5, 2016.[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 the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

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 name contains any USAN stems as of the last USAN updates. The August 30, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 is acceptable from promotional and safety perspective.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 29, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[a] Gao T. Proprietary Name Review for Kisqali (IND 117796). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 April 5. Panorama No. 2016-2863502.

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

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