

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210259Orig1s000

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: August 23, 2017
Application Type and Number: NDA 210259
Product Name and Strength: Calquence (acalabrutinib) capsule, 100 mg
Product Type: Single ingredient
Rx or OTC: Rx
Applicant/Sponsor Name: Acerta Pharma B.V.
Panorama #: 2017-15712155
DMEPA Safety Evaluator: Casmir Ogbonna, PharmD, MBA, BCPS, BCGP
DMEPA Team Leader: Hina Mehta, PharmD

(

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Calquence, which was found conditionally acceptable under IND 118717 on November 8, 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 Hematologic Products (DHP) 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 July 28, 2017, 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 Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 16, 2017, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

^a Rychlik, I. Proprietary Name Review for Calquence (IND 118717). 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 NOV 08. Panorama No. 2016-9658497.

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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CASMIR I OGBONNA
08/23/2017

HINA S MEHTA
08/24/2017