CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216387Orig1Orig2s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	December 13, 2021
Application Type and Number:	NDA 216387
Product Name and Strength:	Calquence (acalabrutinib) tablets, 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	AstraZeneca UK Limited (AstraZeneca)
PNR ID #:	2021-1044724221
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Calquence, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. AstraZeneca did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Calquence (acalabrutinib) was approved on October 31, 2017 under NDA 210259. Calquence is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy; this indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Calquence is currently available as 100 mg oral capsules.

AstraZeneca UK Limited (AstraZeneca) now proposes NDA 216387 acalabrutinib tablets, 100 mg, for the proposed indication for the treatment of adult patients with MCL who have received at least one prior therapy (accelerated approval), and adult patients with Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Thus, AstraZeneca submitted the name, Calquence, for the newly proposed dosage formulation (i.e. tablet) for review under NDA 216387 on October 4, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 4, 2021 for Calquence (acalabrutinib) tablets and the Prescribing Information for Calquence (acalabrutinib) capsules.

Table 1. Relevant Product Information for Calquence (acalabrutinib)		
Product Name	Calquence [proposed] (NDA 216387)	Calquence[a] (NDA 210259)
Initial Approval Date	Under Review	October 31, 2017
Intended Pronunciation	Kal' kwens	
Active Ingredient	acalabrutinib	acalabrutinib
Indication	CALQUENCE is a kinase inhibitor indicated for the treatment of adult patients with: • Mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent	

[a] Calquence [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2019 NOV 21. Available from: https://www.accessdata fda.gov/drugsatfda_docs/label/2019/210259s006s007lbl.pdf

	upon verification and description of clinical benefit in confirmatory trials. • Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).	
Route of Administration	Oral	
Dosage Form	Tablet	Capsule
Strength	100 mg	
Dose and Frequency	100 mg approximately every 12 hours	
How Supplied	Bottle containing 60 tablets with a child-resistant closure	Bottle containing 60 capsules
Storage	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].	

We note AstraZeneca is proposing the new tablet dosage form of acalabrutinib as a maleate salt. Per AstraZeneca, unlike the currently marketed capsules, the proposed tablets will allow for concomitant use Calquence tablets with proton-pump inhibitors or with antacids/H2 receptor antagonists without the need of separating the dosing of the agents.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Calquence.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Calquence would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Hematologic Malignancies 2 (DHM 2) concurred with the findings of OPDP's assessment for Calquence.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Calquence.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[b].

2.2.2 Components of the Proposed Proprietary Name

AstraZeneca did not provide a derivation or intended meaning for the proposed proprietary name, Calquence, in their submission. This proprietary name is comprised of a single word that

[b] USAN stem search conducted on November 3, 2021.

does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On October 14, 2021, the Division of Hematologic Malignancies 2 (DHM 2) did not forward any comments or concerns relating to Calquence at the initial phase of the review.

2.2.4 Evaluation of a Single Proprietary Name for Multiple Dosage Forms

We note that the newly proposed tablets dosage formulation shares the same active ingredient as the currently approved Calquence capsules. It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name (e.g. Renvela and Pradaxa).

Based on our understanding from the Review Team at the time of this review, the proposed tablets dosage formulation is also equivalent on a mg-per-mg basis with the currently approved Calquence capsules. Furthermore, we note that through our routine monitoring we have not identified any medication errors involving name confusion with the proprietary name Calquence. Therefore, given the precedence for using this naming convention, and the absence of any medication errors involving the proprietary name, we find AstraZeneca's proposal to market the proposed product with the proprietary name Calquence acceptable. The difference in the product characteristics between the two dosage formulations for Calquence may be managed through labels and labeling.

Additionally, AstraZeneca "expects all patients receiving acalabrutinib capsules to transition to the tablet formulation" and the intention is to "replace the existing capsule product with the tablet formulation within 9 months and retain the current tradename of Calquence to avoid introducing confusion and disruption to the patient's treatment regimen". In addition, AstraZeneca will disseminate communication materials to physicians, pharmacists, and patients regarding the new acalabrutinib tablet dosage form.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 2 communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2). At that time we also requested additional information or concerns that could inform our review. On December 13, 2021, the Division of Hematologic Malignancies 2 (DHM 2) stated no additional concerns with the proposed proprietary name, Calquence.

3 CONCLUSION

The proposed proprietary name, Calquence, 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 ASTRAZENECA UK LIMITED

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 submission, received on October 4, 2021, 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.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [c]

[c] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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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