CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210874Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	October 19, 2018
Application Type and Number:	NDA 210874
Product Name and Strength:	Qternmet XR (dapagliflozin/ saxagliptin/ metformin hydrochloride extended release), tablets dapagliflozin 2.5 mg/saxagliptin 2.5 mg/metformin 1,000 mg dapagliflozin 5 mg/saxagliptin 2.5 mg/metformin 1,000 mg dapagliflozin 5 mg/saxagliptin 5 mg/metformin 1,000 mg dapagliflozin 10 mg/saxagliptin 5 mg/metformin 1,000 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	AstraZeneca
Panorama #:	2018-24782964
DMEPA Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader:	Hina Mehta, PharmD
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Qternmet XR, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. AstraZeneca submitted an external name study, conducted by (b) (4), for this proposed proprietary name which was reviewed previously.[a]

1.1 REGULATORY HISTORY

AstraZeneca previously submitted the proposed proprietary name, Qternmet XR, for review under IND 131385 and the Division of Medication Error Prevention and Analysis (DMEPA) found the name acceptable on October 16, 2017.[a]

The proposed name was resubmitted for review under NDA 210874 on July 26, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 26, 2018.

- Intended Pronunciation: KUE-turn-met ECKS-AR
- Active Ingredients: dapagliflozin/saxagliptin/metformin extended release
- Indication of Use: to improve glycemic control in adults with type 2 diabetes mellitus
- Route of Administration: oral
- Dosage Form: tablet
- Strengths: 2.5 mg/2.5 mg/1,000 mg, 5 mg/2.5 mg/1,000 mg, 5 mg/5 mg/1,000 mg and 10 mg/5 mg/1,000 mg
- Dose and Frequency: Usual dosage is 5 mg/5 mg/1000 mg once daily; the maximum daily dose is 5 mg/5 mg/1,000 mg
- How Supplied: bottles
- Storage: room temperature (20°C to 25°C) with excursions permitted between 15°C and 30°C
- Reference Listed Drug/Reference Product: n/a

2 RESULTS

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

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[a] Ogbonna C. Proprietary Name Review for Qternmet XR (IND 131385). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Oct 16. Panorama No. 2017-14547994.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product per their August 16, 2018 email. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Qternmet XR, is derived from the names of currently approved products: Qtern and metformin extended-release (XR). This proprietary name is comprised of a root name, Qternmet, and the modifier "XR" to indicate that the drug is an extended-release formulation.

We note that the prefix and infix "Qtern-" represent the currently approved product, Qtern, containing dapagliflozin and saxagliptin, and the suffix "-met" represents the metformin active ingredient. We evaluated the representation of each active ingredient in the proposed proprietary name in our previous review and maintain our conclusion that the name is not misleading.[c]

Additionally, we evaluated the use of the modifier "XR" to convey that the product is an extended-release dosage form in our previous review.[c] Assuming that the Agency determines that the product is a modified-release formulation, we maintain our conclusion that modifier "XR" is not misleading; thus, we find the modifier "XR" acceptable for this product.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE August 18, 2018 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Forty-eight (n=48) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

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[b] USAN stem search conducted on September 19, 2018.

[c] Ogbonna C. Proprietary Name Review for Qternmet XR (IND 131385). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Oct 16. Panorama No. 2017-14547994

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