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*APPLICATION NUMBER:*

**209091Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	July 8, 2016
<b>Application Type and Number:</b>	NDA 209091
<b>Product Name and Strength:</b>	Qtern (saxagliptin and dapagliflozin), tablet, 5 mg saxagliptin/10 mg dapagliflozin
<b>Product Type:</b>	Multi-Ingredient Product
<b>Rx or OTC:</b>	RX
<b>Applicant/Sponsor Name:</b>	AstraZeneca
<b>Panorama #:</b>	2016-7793681
<b>DMEPA Primary Reviewer:</b>	Ariane O. Conrad, PharmD, BCACP, CDE
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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Qtern, 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. The Applicant submitted an external name study, conducted by [REDACTED]<sup>(b) (4)</sup> for this product, submitted under IND 118840.

### 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Qtern, on July 30, 2014 under IND 118840. The Division of Medication Error Prevention and Analysis (DMEPA) found the name conditionally acceptable in OSE Review #2014-25982, dated October 9, 2014<sup>1</sup>. [REDACTED]<sup>(b) (4)</sup>

### 1.2 PRODUCT INFORMATION

The following product information is provided in the April 29, 2016 proprietary name submission and the April 27, 2016 labeling submission.

- Intended Pronunciation: KUE-turn
- Active Ingredient: saxagliptin and dapagliflozin
- Indication of Use: as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) [REDACTED]<sup>(b) (4)</sup>
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 5 mg saxagliptin/10 mg dapagliflozin
- Dose and Frequency: 1 tablet once daily in the morning
- How Supplied: bottles of 30, 90, or 500 tablets
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [USP controlled room temperature]

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<sup>1</sup> Mistry M. Proprietary Name Review for Qtern (IND 118840). 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); 2014 Oct 9. 19 p. OSE RCM No. 2014-25982.

<sup>2</sup> [REDACTED]<sup>(b) (4)</sup>

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product via their May 10, 2016 email. DMEPA and 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<sup>3</sup>.

#### 2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Qtern in their submission. This proprietary name is comprised of a single word that 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 *FDA Name Simulation Studies*

One hundred twenty-one (121) practitioners participated in DMEPA's prescription studies with one response from the inpatient order overlapping with the existing name Ativan and one response from the verbal prescription overlapping with the existing name quetiapine. We evaluated these names in our review and determined that confusion between these Qtern and quetiapine or Qtern and Ativan is unlikely for the following reasons:

- Ativan contains three syllables while Qtern contains two syllables. In addition, the syllables of this name (a-ti-van) sound different than Qtern (q-tern).
- Ativan is available in three different strengths (0.5 mg, 1 mg, and 2 mg) that do not overlap with the dose for Qtern. During prescribing, the strength of Ativan would have to be indicated while that information could be omitted for Qtern, which is only available in a single strength.
- Quetiapine contains 4 syllables while Qtern only contains 2 syllables. The middle syllables of this name (que-ti-a-pine) sound different than Qtern.
- The length of the name quetiapine is longer than Qtern. In addition, the infix and suffix of quetiapine (-tiapine) appears dissimilar from Qtern when scripted.

Given the orthographic, phonetic and strength differences between Ativan and Qtern, it is unlikely that confusion may occur with this name pair. Therefore, it is little likelihood of confusion between these two names. In addition, the orthographic and phonetic

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<sup>3</sup>USAN stem search conducted on May 11, 2016.

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