CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210874Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

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)

Date of This Memorandum:	May 1, 2019
Requesting Office or Division:	Division of Metabolism and Endocrinology Products (DMEP)
Application Type and Number:	NDA 210874
Product Name and Strength:	Qternmet XR (dapagliflozin, saxagliptin, and metformin HCl) extended release tablet, 2.5 mg/(b) (4) mg/1,000 mg, 5 mg/2.5 mg/1,000 mg, 5 mg/5 mg/1,000 mg, 10 mg/5 mg/1,000 mg
Applicant/Sponsor Name:	AstraZeneca Pharmaceuticals
FDA Received Date:	May 1, 2019
OSE RCM #:	2018-1448-2
DMEPA Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

Division of Metabolism and Endocrinology Products (DMEP) requested that we review the revised trade and sample container and carton labeling for Qternmet XR (Appendix A) to determine if they are acceptable from a medication error perspective. The sponsor proposed additional revisions to the carton and container to correspond with Agency recommendations for the ingredient descriptions in Section 11 Description of the prescribing information. Our prior labeling determined that the trade container labels and sample carton labeling for Qternmet XR were acceptable. [a]

2 CONCLUSION

The revised trade container labels and sample carton labeling for Qtern are acceptable from a medication error perspective. We have no further recommendations at this time.

[a] DeGraw S. Review of Revised Label and Labeling for Qternmet XR (NDA 210874). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 April 23. RCM No.: 2018-1448-1.

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/

ARIANE O CONRAD
05/01/2019 03:53:42 PM

HINA S MEHTA
05/01/2019 05:25:30 PM

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
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)

Date of This Memorandum:	April 23, 2019
Requesting Office or Division:	Division of Metabolism and Endocrinology Products (DMEP)
Application Type and Number:	NDA 210874
Product Name and Strength:	Qternmet XR (dapagliflozin, saxagliptin, and metformin HCl) extended-release tablets 2.5 mg/(b) mg/1,000 mg 5 mg/2.5 mg/1,000 mg 5 mg/5 mg/1,000 mg 10 mg/5 mg/1,000 mg
Applicant/Sponsor Name:	AstraZeneca
FDA Received Date:	April 18, 2019
OSE RCM #:	2018-1448-1
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

The Division of Metabolism and Endocrinology Products requested we review the revised container labels for Qternmet XR (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review[a] and an information request sent on April 9, 2019.[b]

2 CONCLUSION

We note our recommendation of adding a comma to all numbers greater than or equal to 1,000 in our previous review. AstraZeneca responded with their preference to display 1000 without a comma to avoid potential confusion when both a comma and decimal point are included within the same strength statement and visual field. In addition, the proposal to display 1000 without a

[a] DeGraw, S. Label and Labeling Review for Qternmet (dapagliflozin-saxagliptin-metformin) NDA 210874. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JAN 23. RCM No.: 2018-1448.
[b] https://darrts.fda.gov//darrts/faces/ViewDocument?documentId=090140af804eb815&_afrRedirect=1801611992296345

comma for all dosage strengths provides for consistency across dose presentations. We note the exclusion of the comma would not likely lead to confusion as there are three parts to the strength presentation as the product contains three separate components.

The revised container labels are acceptable from a medication error perspective. We have no additional recommendations at this time.

4 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.