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APPLICATION NUMBER:

209091Orig1s000

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: February 24, 2017

Requesting Office or Division: Division of Metabolism and Endocrinology Products (DMEP)

Application Type and Number: NDA 209091

Product Name and Strength: Qtern (dapagliflozin and saxagliptin), tablets 5 mg/10 mg

Submission Date: February 24, 2017

Applicant/Sponsor Name: AstraZeneca

OSE RCM #: 2016-1009-4

DMEPA Primary Reviewer: Ariane O. Conrad, PharmD, BCACP, CDE

DMEPA Team Leader: Hina Mehta, PharmD

1 PURPOSE OF MEMO

Division of Metabolism and Endocrinology Products (DMEP) requested that we review the revised commercial container label, professional sample carton labeling, and professional sample blister cards for Qtern (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

2 CONCLUSION

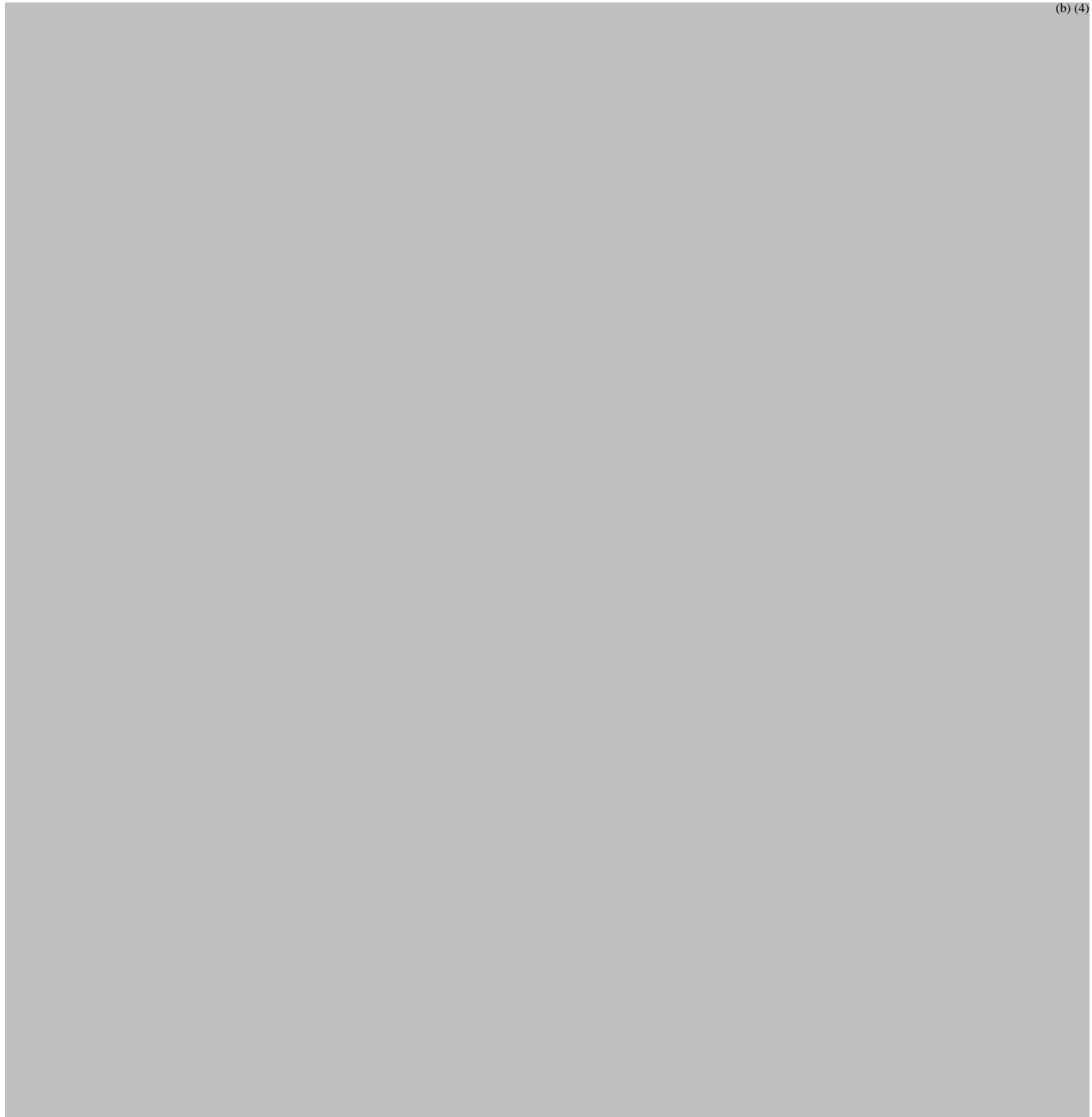
The revised commercial container labels, professional sample carton labeling, and professional sample blister cards for Qtern are acceptable from a medication error perspective. We have no further recommendations at this time.

^a Conrad A. Label and Labeling Review Memo for Qtern (NDA 209091). 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); 2017 Feb 21. 4p. OSE RCM No.: 2016-1009-3.

APPENDIX A. LABEL AND LABELING SUBMITTED ON FEBRUARY 24, 2017

Commercial Container Labels

(b) (4)



Professional Sample Blister Cards



Professional Sample Carton Labeling



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/s/

ARIANE O CONRAD
02/24/2017

HINA S MEHTA
02/24/2017

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