CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215859Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
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)

Date of This Memorandum:	December 7, 2021
Requesting Office or Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	NDA 215859
Product Name and Strength:	Xarelto (rivaroxaban) for oral suspension, 1 mg/mL (after reconstitution)
Applicant/Sponsor Name:	JANSSEN PHARMACEUTICALS INC
OSE RCM #:	2021-1248-1
DMEPA 2 Safety Evaluator:	Ebony Whaley, PharmD, BCPPS
DMEPA 2 Team Leader (Acting):	Colleen Little, PharmD

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised Instructions for Use (IFU), container label, and carton labeling received on November 24, 2021 for Xarelto. The Division of Non-Malignant Hematology (DNH) requested that we review the revised IFU, container label, and carton labeling for Xarelto (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

We determined that the revised IFU, container label, and carton labeling are acceptable from a medication error perspective, and we do not have additional recommendations at this time.

Regarding the revised IFU, we note the Applicant did not increase the prominence of the caution statement in IFU Step 4 as previously recommended. The Applicant noted that they

[a] Whaley, E. Human Factors Results and Label and Labeling Review for Xarelto (NDA 215859). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2021 NOV 15. RCM No.: 2021-1248 2021-1257.

previously implemented post-validation revisions to make the caution statement more noticeable (i.e., addition of the Caution symbol and removal [redacted]). We acknowledge the Applicant's previously implemented revisions are intended to increase the prominence of the caution statement and to address performance in the HF validation study. As such, in this instance, we determined that additional IFU revisions to IFU Step 4 are not needed at this time.

Regarding the revised container label and carton labeling, we note the Applicant did not implement our recommendation to include the total volume after reconstitution on the container label and carton labeling. The Applicant stated that inclusion of the total volume after reconstitution could cause confusion to the pharmacist (e.g., a pharmacist who sees the [redacted] mL total volume on the label may be confused about how much water to use and could incorrectly reconstitute with [redacted] mL of water). We note the carton labeling and Prescribing Information inform users of the volume needed for reconstitution (i.e., 150 mL) and the total contents of the bottle (i.e., 155 mg of rivaroxaban). In this instance, we determined that additional container label and carton labeling revisions are not needed at this time.

3 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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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/

EBONY A WHALEY
12/07/2021 08:58:28 AM

COLLEEN L LITTLE
12/07/2021 09:38:25 AM

HUMAN FACTORS STUDY REPORT AND LABELS AND LABELING 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:	November 15, 2021
Requesting Office or Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	NDA 215859
Product Type: Drug Constituent Name and Strength Device Constituent:	Combination product Xarelto (rivaroxaban) for oral suspension, 1 mg/mL (after reconstitution) Oral syringe
Rx or OTC:	Rx
Applicant/Sponsor Name:	Janssen Pharmaceuticals, Inc.
Submission Date:	6/22/2021; 8/30/2021
OSE RCM #:	2021-1248; 2021-1257
DMEPA 2 Safety Evaluator:	Ebony Whaley, PharmD, BCPPS
DMEPA 2 Team Leader (Acting):	Colleen Little, PharmD
DMEPA 2 Associate Director for Human Factors :	Lolita White, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

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