CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	May 12, 2011
Through:	Carol Holquist, RPh, Division Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Denise V. Baugh, PharmD, BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name and Strengths, Application Types/Numbers:	Xarelto (Rivaroxaban) Tablets 10 mg NDA 022406 (Division of Hematology Products) Xarelto (Rivaroxaban) Tablets (b) (4) 20 mg NDA 202439 (Division of Cardio-Renal Products)
Applicant:	Johnson & Johnson Pharmaceutical Research & Development, LLC on behalf of Ortho-McNeil-Janssen-Pharmaceuticals, Inc.
OSE RCM #:	2011-512 2011-437

***** Note: This review contains proprietary and confidential information that should not be released to the public.****

CONTENTS

EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Xarelto for Rivaroxaban Tablets. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Xarelto, acceptable for this product. DMEPA will notify the Applicant of these findings via letter

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request received from Johnson & Johnson Pharmaceutical Research & Development, LLC on behalf of Ortho-McNeil-Janssen-Pharmaceuticals, Inc., submitted February 18, 2011, to evaluate the proposed proprietary name, Xarelto, regarding promotional concerns and potential name confusion with other proprietary or established drug names based on the product characteristics provided by the Applicant.

The Applicant also submitted container labels and carton labeling which will be reviewed under separate cover (OSE Review #2011-438 and #2011-513).

1.2 REGULATORY HISTORY

Rivaroxaban is the established name for the proposed proprietary name, Xarelto, previously found acceptable by DMEPA (OSE Review # 2007-1832 dated April 30, 2009) under IND# 64,892. At that time the dose was 10 mg taken orally once daily and the indication was for the prophylaxis of deep vein thrombosis and pulmonary embolism in patients undergoing hip replacement or knee replacement surgery. No other indication or treatment regimen was proposed at that time.

1.3 PRODUCT INFORMATION

Xarelto is a new molecular entity which will have two different indications and corresponding treatment regimens. Details are described below.

1.3.1 Prophylaxis of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)

Xarelto (Rivaroxaban Tablets) is indicated for the prophylaxis of deep vein thrombosis and pulmonary embolism in patients undergoing hip replacement or knee replacement surgery. The recommended oral dose is 10 mg taken once daily with or without food. The initial dose should be taken at least 6 to 10 hours after surgery once hemostasis has been established. Xarelto should be used with caution in patients with CrCl 15 mL/minute to less than 30 mL/minute. It is not recommended in patients with CrCl less than 15 mL/minute. The treatment duration is 35 days (hip surgery) to 14 days (knee surgery). Xarelto will be supplied in bottles of 30 and in a (b) (4) carton containing 10 blister cards of 10 tablets each.

1.3.2 Prevention of Stroke and Systemic Embolism

Xarelto (Rivaroxaban Tablets) is indicated for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation. (b) (4)

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Xarelto.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'X' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to 'Xarelto', the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (three, upper case 'X', lower case 'l' and 't'), down-strokes (none), cross-strokes (two, upper case 'X' and lower case 't') and dotted letters (none). Additionally, several letters in Xarelto may be vulnerable to ambiguity when scripted (see Appendix B). As such, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Xarelto.

When searching to identify potential names that may sound similar to Xarelto, the DMEPA staff searches for names with similar number of syllables (three), stresses (XA-rel-to, xa-REL-to, or za-rel-TO), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary, such as the letter 'x' which may be interpreted as 'z' and the letters 'to' may be interpreted as 'tow'.

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[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

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