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APPLICATION NUMBER:
202343Orig1s000

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
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: September 26, 2011

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Drug Name(s): Juvisync (Sitagliptin and Simvastatin) Tablets

Strengths: 100 mg/10 mg, 100 mg/20 mg, 100 mg/40 mg

Application Type/Number: NDA 202343

Applicant/sponsor: Merck

OSE RCM #: 2011-3271

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Juvisync, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

The Applicant, Merck, submitted the proprietary name request for Juvisync Tablets on September 2, 2011. The Applicant had submitted two names previously, (b) (4) which was found unacceptable in OSE review # 2011-2427 and (b) (4) which was withdrawn by the Applicant on September 2, 2011.

Additionally, a label and labeling review (OSE review # 2011-300) was also completed on June 20, 2011. The label and labeling recommendations were sent to the Applicant.

1.2 PRODUCT INFORMATION

Juvisync is a combination product which contains Sitagliptin and Simvastatin. Juvisync is indicated for glycemic control in the setting of Type 1 diabetes and to decrease cholesterol. The proposed strengths of Juvisync include; 100 mg/10 mg, 100 mg/20 mg, and 100 mg/40 mg tablets. The recommended dose and frequency of Juvisync is one tablet by mouth once daily. Juvisync will be available in physician samples and bottles of 30, 90 and 1000 tablets and can be stored at room temperature.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolic and Endocrinology Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall evaluation.

2.2.1 *United States Adopted Names (USAN) SEARCH*

The September 9, 2011 United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

Per the Applicant and DMEPA's evaluation of the proprietary name, Juvisync, is a coined term that has no intrinsic meaning. 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 can contribute to medication error or render the name unacceptable.

2.2.3 FDA Name Simulation Studies

Twenty nine practitioners participated in DMEPA’s prescription studies. The most common misinterpretation in the written study was with the first letter ‘J’ for ‘T’ and ‘L’. The most common misinterpretations in the voice study was confusion with vowels ‘i’ for ‘a’, ‘e’, and ‘o’ and ‘y’ for ‘i’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, September 14, 2011 e-mail, the Division of Metabolic and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed name, Juvisync. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Juvisync identified by the primary reviewer (PR), the Expert Panel Discussion (EPD), other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar		Sound Similar		Look and Sound Similar	
Name	Source	Name	Source	Name	Source
Jenloga	EPD	Nuvaring	EPD	Juvisync	EPD
Tasigna	EPD	Jantoven	EPD	Januvia	EPD
Tikosyn	EPD			(b) (4)	EPD
Tussigon	EPD				
(b) (4)	EPD				
(b) (4)	EPD				
Invega	EPD				
Invagesic	EPD				
Visudyne	EPD				
Jevantique	EPD				
Junovan	EPD				
Junifer	EPD				
Enjuvia	EPD				
(b) (4)	PR				
(b) (4)	PR				

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