CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204569Orig1s000

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 Memorandum

Date:	March 7, 2014
Reviewer:	Jacqueline Sheppard, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	Julie Neshiewat, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Belsomra (Suvorexant) Tablets 5 mg, 10 mg, 15 mg, 20 mg
Application Type/Number:	NDA 204569
Applicant/Sponsor:	Merck Sharp and Dohme Corp.
OSE RCM #:	2014-16964

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

1 INTRODUCTION

The proposed proprietary name, Belsomra, was found acceptable in OSE Review # 2013-1912, dated October 23, 2013 under IND 101847. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Belsomra, is acceptable from both a promotional and safety perspective under the NDA 204569.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

1.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Belsomra, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your February 19, 2014 submission are altered, the name must be resubmitted for review.

2 REFERENCES

1. OSE Review # 2013-1912: Proprietary Name Review for Belsomra (Suvorexant) Tablets, October 23, 2013.

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/s/

JACQUELINE E SHEPPARD
03/07/2014

JULIE V NESHIEWAT
03/07/2014

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:	April 17, 2013
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	(b) (4) (Suvorexant) Tablets 15 mg, 20 mg, 30 mg, 40 mg
Application Type/Number:	NDA 204569
Applicant/Sponsor:	Merck Sharp & Dohme Corp.
OSE RCM #:	2013-218

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/s/

JULIE V NESHIEWAT
04/17/2013

IRENE Z CHAN
04/17/2013

CAROL A HOLQUIST on behalf of KELLIE A TAYLOR
04/17/2013
Signing on behalf of Kellie Taylor

CAROL A HOLQUIST
04/17/2013