

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**204569Orig1s000**

***Trade Name:* Belsomra**

***Generic Name:* suvorexant**

***Sponsor:* Merck & Co, Inc.**

***Approval Date:* August 13, 2014**

***Indication:* For insomnia, characterized by difficulties with sleep onset and/or maintenance**

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*APPLICATION NUMBER:*  
**204569Orig1s000**

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*APPLICATION NUMBER:*

**204569Orig1s000**

**APPROVAL LETTER**



NDA 204569

**NDA APPROVAL**

Merck & Co., Inc.  
126 Lincoln Avenue  
P.O. Box 2000, RY 33-208  
Rahway, NJ 07065

Attn: Nadine Margaretten, Ph.D.  
Director, Worldwide Regulatory Affairs

Dear Dr. Margaretten:

Please refer to your New Drug Application (NDA) dated August 30, 2012, received August 30, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Belsomra (suvorexant, MK-4305) 5, 10, 15 and 20 mg oral tablets.

We also refer to our approval letter dated August 13, 2014, which contained the following error:

**Section 9.1 Controlled Substance**

BELSOMRA contains suvorexant, a controlled substance.

Since scheduling of Belsomra has not been finalized this statement is incorrect. We have revised this section of the Prescribing Information (PI) as follows:

**Section 9.1 Controlled Substance**

BELSOMRA contains suvorexant, **(schedule to be determined after DEA review)**.

This replacement approval letter and labeling incorporates the correction of the error. The effective approval date will remain August 13, 2014, the date of the original approval letter.

**CONTROLLED SUBSTANCE SCHEDULING**

The final scheduling of this product under the Controlled Substances Act is currently proceeding, but not yet complete as of the date of this letter. We remind you that on August 3, 2014, you agreed not to market this drug until the Drug Enforcement Administration has made a final scheduling decision. We further note that, when the scheduling is finalized, you will need to make appropriate revisions to the package insert, the patient package insert and the carton and immediate-container labels through supplementation of your NDA. This would include the statements detailing the scheduling of Belsomra in the labeling, as required under 21 CFR 201.57(a)(2) and (c)(10)(i).

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the patient package insert, and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 204569.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. We have considered several potential pediatric populations in which difficulties with insomnia could be evaluated, and have concluded that there are insufficient data to support the appropriateness of studies in any pediatric population, making it impossible to enroll an appropriate target population for a trial.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

### **MEDWATCH-TO-MANUFACTURER PROGRAM**

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at

<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm166910.htm>.

### **POST APPROVAL FEEDBACK MEETING**

New molecular entities and new biologics qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, call Cathleen Michaloski, Sr. Regulatory Project Manager, by email [Cathleen.michaloski@fda.hhs.gov](mailto:Cathleen.michaloski@fda.hhs.gov) or by phone (301) 796-1123.

Sincerely,

*{See appended electronic signature page}*

Ellis F. Unger, M.D.  
Director  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ELLIS F UNGER  
08/13/2014



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We acknowledge receipt of your amendments dated:

September 21, 2012	August 21, 2013
October 4, 2012	October 24 and 28, 2013
November 2 and 20, 2012	February 14 and 19, 2014
December 7, 12, 17, 20 and 21, 2012	April 2 and 30, 2014
January 17, 2013	May 21 and 30, 2014
February 5 and 28, 2013	June 25, 2014
March 11, 27 and 29, 2013	July 10, 16, 28 and 31, 2014
April 9, 11, 12, 19, 23 and 29, 2013	August 6, 7, 11 and 12, 2014
May 22 and 31, 2013	
June 5, 2013	

The February 14, 2014, submission constituted a complete response to our June 28, 2013, action letter.

This new drug application provides for the use of Belsomra (suvorexant) oral tablets for insomnia, characterized by difficulties with sleep onset and/or maintenance.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

### **CONTENT OF LABELING**

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Ellis F. Unger, M.D.  
Director  
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Center for Drug Evaluation and Research

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/s/  
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ELLIS F UNGER  
08/13/2014