DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204569/S-004

**SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp.
Attention: Nadine Margaretten, PhD
Director, Worldwide Regulatory Affairs
126 East Lincoln Ave
P.O. Box 2000 RY34-B188
Rahway, NJ 07065

Dear Dr. Margaretten:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 13, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Belsomra (suvorexant) 5 mg, 10 mg, 15 mg, and 20 mg film coated tablets.

We acknowledge receipt of your amendment dated May 17, 2016, which constituted a complete response to our May 13, 2016, action letter.

This Prior Approval supplemental new drug application proposes a modification of subsection 9.2 (Abuse) of the Prescribing Information to better describe the effect of suvorexant on reaction time as well as the addition of "abnormal dreams" to the Medication Guide.

## APPROVAL & LABELING

We have completed our review of this supplemental 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

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 package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

**PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf ).

**REPORTING REQUIREMENTS**

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

If you have any questions, contact Dr. Brendan Muoio, Regulatory Project Manager, at (240) 402-4518 or brendan.muoio@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Tiffany Farchione, MD
Deputy Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of 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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BRENDAN MUOIO
05/27/2016

TIFFANY R FARCHIONE
05/27/2016