



NDA 020415/S-039

APPROVAL LETTER

Organon USA LLC
Attention: Alok Gokhale
Sr. Scientist, Regulatory Liaison
4000 Chemical Road
Suite 500
Plymouth Meeting, PA 19462

Dear Alok Gokhale:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 24, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Remeron (mirtazapine) oral tablets.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the following changes:

- a) Addition of [REDACTED] (b) (4)
with FEI: [REDACTED] (b) (4) as an alternate site for primary and secondary packaging
- b) Addition of alternate [REDACTED] (b) (4)
- c) Addition of [REDACTED] (b) (4) [REDACTED] (b) (4)
[REDACTED] (b) (4)

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on January 24, 2025, 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020415/S-039.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Teshara Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

Sincerely,

{See appended electronic signature page}

Vilayat Sayeed, Ph.D.
Director
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Container Labeling



Vilayat
Sayeed

Digitally signed by Vilayat Sayeed

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