DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-415/S-016
NDA 21-208/S-008

Organon Inc.
Attention: Ana Arango Bossard
Associate Director, Regulatory Affairs, CNS
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Dear Ms. Arango Bossard:

We acknowledge receipt of your supplemental new drug applications dated May 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Remeron (mirtazapine) Immediate-Release (NDA 20-415) and Remeron SolTab (mirtazapine) Orally Disintegrating Tablets (NDA 21-208).

These supplemental applications, submitted under "Changes Being Effected", provide for the following changes to product labeling as requested in our Agency letter dated March 19, 2004, and revised in an electronic communication to you from Paul David, of this office, on April 19, 2004:

1. The addition of a new subsection under **WARNINGS** entitled **Clinical Worsening and Suicide Risk**.
2. Revisions to the **PRECAUTIONS-Information for Patients** section.
3. Delete the section in **PRECAUTIONS-General** entitled “Suicide”.
4. Add a reference to the **WARNINGS** section at the end of the **PRECAUTIONS- Pediatric Use** section, i.e., (see **WARNINGS-Clinical Worsening and Suicide Risk**).

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your draft labeling dated May 18, 2004, which incorporates all of the revisions listed above. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted on May 18, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDAs 20-415/S-016 and 21-208/S-008.” Approval of these submissions by FDA is not required before the labeling is used.

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

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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