DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-415/S-015

Organon Inc.
Attention: Albert P. Mayo
Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, New Jersey 07052

Dear Mr. Mayo:

Please refer to your supplemental new drug application dated June 7, and received June 10, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Remeron (mirtazapine) 15 mg, 30 mg, and 45 mg tablets.

We acknowledge receipt of your correspondence dated September 13, 2002, pertaining to the labeling changes submitted in your June 7, 2002 labeling supplement.

We additionally refer to an Agency letter dated February 27, 2002, requesting labeling changes as well as a conference call between the Agency and representatives from Organon dated June 4, 2002 to discuss the changes as requested in our February 27, 2002 letter.

This "Prior Approval" supplemental new drug application proposes the addition of a statement regarding weight gain in pediatric patients treated with Remeron in the **PRECAUTIONS-Increased Appetite/Weight Gain** and **PRECAUTIONS-Pediatric Use** sections of labeling.

We note your agreement in correspondence dated September 13, 2002, to implement these changes, verbatim, as requested in our February 27, 2002 letter.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

We additionally note your concern that the Agency denied a conference call with Organon to discuss the labeling changes proposed in your June 6, 2002 submission. The Agency believed that the conference call with Organon held on June 4, 2002 was sufficient, alone, to discuss this issue. Additionally, Organon's changes submitted on June 6, 2002, proposed the addition of a sentence regarding drop-out rate in order to be "consistent" with the adult statement on this point. We believed that the addition of this statement tends to minimize the actual drug effect here, and this was conveyed to Organon by Mr. Paul David of this Agency.

In regard to your assertion that this labeling supplement should be linked to your pediatric efficacy supplement, we do not concur with this administrative procedure.

We are additionally requesting that you submit a labeling supplement with the agreed upon changes to the above sections of labeling to the Remeron Soltab (mirtazapine) Orally Disintegrating Tablet NDA, 21-108, since the above safety changes would also be applicable to this bioequivalent product.

The final printed labeling (FPL) must be identical to the labeling as requested in our February 27, 2002 letter.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-415/S-015." Approval of this submission 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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