



NDA 20415/S-026

NDA 21208/S-016

SUPPLEMENT APPROVAL

Organon USA Inc.
Attention: Lori Yamashita, Manager, Regulatory Affairs
351 Sumneytown Pike, P.O. Box 1000
North Wales, PA 19454-1009

Dear Ms. Yamashita:

Please refer to your Supplemental New Drug Applications (sNDA) dated April 20, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Remeron (mirtazapine) 15 mg, 30 mg, and 45 mg Tablets (NDA 20415) & Remeron SolTab (mirtazapine) 15 mg, 30 mg, and 45 mg orally disintegrating tablets (NDA 21208).

We acknowledge receipt of your amendments dated August 3, 2012, September 14, 2012, and October 19, 2012.

These "Prior Approval" supplemental new drug applications provide for class labeling revisions to the **Contraindications, Warnings, Dosage And Administration, & Medication Guide** regarding serotonin toxicity associated with the co-administration of linezolid and methylene blue as requested in an Agency supplement request letter dated March 5, 2012.

We have completed our review of these supplemental applications, as amended. They are 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(1)] 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 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).

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, email LCDR Hiren Patel, Pharm.D., Senior Regulatory Project Manager, at Hiren.Patel@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

/s/

THOMAS P LAUGHREN
10/30/2012