



NDA 20415/S-031
NDA 21208/S-021

SUPPLEMENT APPROVAL

Organon USA Inc.
Attention: Siyoung Ahn, Associate Director, Worldwide Regulatory Affairs
126 East Lincoln Avenue, P.O. Box 2000
Rahway, NJ 07065

Dear Ms. Ahn:

Please refer to your Supplemental New Drug Applications (sNDA) dated June 13, 2014, 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 also refer to our letter dated May 13, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for drugs to treat major depressive disorder. This information pertains to the risk of angle-closure glaucoma.

These supplemental new drug applications provide for revisions to the labeling for Remeron and Remeron SolTab consistent with our May 13, 2014 letter.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the revisions agreed upon in an email communication dated July 2, 2014, between you and Terry Harrison, of this Agency.

We note that your June 13, 2014, submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 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 Hiren Patel, Regulatory Project Manager, at hiren.patel@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
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/

MITCHELL V Mathis
07/18/2014