



NDA 22117/S-013

SUPPLEMENT APPROVAL

Organon USA Inc.
Attention: Irene Nunes, OD, PhD
Director, Worldwide Regulatory Affairs
P.O. Box 2000, RY 33-204
Rahway, NJ 07065

Dear Dr. Nunes:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 13, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Saphris (asenapine) 5 mg and 10 mg sublingual tablets.

We acknowledge receipt of your amendment dated October 18, 2012.

The October 18, 2012, amendment constituted a complete response to our October 1, 2012, action letter.

This "Changes Being Effected" supplemental new drug application proposes editorial changes and elimination of the **Recent Major Changes** from the **Highlights** section of labeling.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. We remind you that these approved changes do not encompass your Prior Approval supplement dated August 26, 2011, providing for metabolic changes; and your Changes Being Effected supplement dated October 7, 2011, providing for revisions to Section 6 Adverse Reactions, as these supplements are still under review.

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), 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, call Sharonjit Sagoo, Regulatory Project Manager, at sharonjit.sagoo@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
11/08/2012