DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22117/S-011

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Forest Laboratories, Inc.
Attention: Patricia Pacificador, Pharm.D.
Senior Manager, Regulatory Affairs
Harborside Financial Center
Plaza V, Suite 1900
Jersey City NJ, 07311

Dear Dr. Pacificador:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 26, 2011, 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 amendments dated October 25, 2013, December 20, 2013, August 6, 2014, September 23, 2014, and October 8, 2014.

The October 25, 2013, submission constituted a complete response to our August 23, 2013, action letter.

This "Prior Approval" supplemental new drug application provides for an addition to labeling under Warnings and Precautions, section 5, entitled Metabolic Changes, and was submitted in response to a postmarketing commitment issued in the approval letter of August 13, 2009.

1496-8 The Division of Psychiatry Products is evaluating the effects of atypical antipsychotic drugs on metabolic parameters (e.g., weight, lipids, and glucose). We request that you conduct and submit analyses of these parameters, using data from your clinical development program. See Appendix A for the requested analyses. Results of the requested analyses may be submitted in stages. Specifically, information from placebo-controlled trials (all subject groups), comparator controlled trials (all subjects groups), and combined controlled and uncontrolled data (all subjects), may be submitted separately, as they are completed.

APPROVAL, LABELING, & FULFILLMENT OF POSTMARKETING COMMITMENT

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 have also concluded that the above commitment was fulfilled.

We remind you that there are postmarketing commitments listed in the August 13, 2009 approval letter that are still open.

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, text for the 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 that includes labeling changes 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 Keith Kiedrow, Pharm.D., RAC, Senior Regulatory Project Manager, at (301) 796-1924.

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

ENCLOSURES:
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
10/21/2014