DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21323/S-044; 21365/S-032

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Forest Laboratories, Inc.
Attention: Nadia C. Success
Associate, Regulatory Affairs
Harborside Financial Center, Plaza V
Jersey City, NJ 07311

Dear Ms. Success:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received on March 12, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 21323/S-044, Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 20 mg tablets and NDA 21365/S-032, Lexapro (escitalopram oxalate) 5 mg base/5 ml oral solution.

We acknowledge receipt of your amendment dated July 22, 2014.

These "Prior Approval" supplemental new drug applications contain the final study report and proposed labeling modifications based upon findings from the following postmarketing commitment (PMC 1088-1) issued in the March 19, 2009 approval letter.

1088-1 Long-Term Safety Study

An open-label, 24-week safety study with escitalopram in children ages 7-11.

APPROVAL, LABELING, & FULFILLMENT OF POSTMARKETING COMMITMENT

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. We have also concluded that the above commitment has been fulfilled. This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our March 19, 2009, letter.

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 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, please contact CAPT William Bender, Senior Regulatory Project Manager at william.bender@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
10/31/2014