DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020822/S-042
NDA 021046/S-019

SUPPLEMENT APPROVAL

Forest Laboratories, Inc.
Attention: Debleena Sengupta, Ph.D., RAC
Senior Manager, Regulatory Affairs
Harborside Financial Center
Plaza V, Suite 1900
Jersey City, NJ 07311

Dear Dr. Sengupta:

Please refer to your Supplemental New Drug Application (sNDA) dated March 5, 2012 (NDAs 020822/S-042, 021046/S-019), submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Celexa (citalopram hydrobromide) 10 mg, 20 mg, and 40 mg tablets (NDA 020822), and Celexa (citalopram hydrobromide) 10 mg/5 ml oral solution (NDA 021046).

Reference is also made to an Agency letter dated February 14, 2012 requesting revisions to the QT-Prolongation and Torsade de Pointes sections and the March 21, 2012 email regarding minor modifications to the CYP2C19 section of the Celexa labeling.

The March 5, 2012, submission constituted a response to our February 14, 2012 prior approval supplement request letter. The Prior Approval Labeling Supplements (020822/S-042 and 021046/S-019) provide for revisions related to the QT-Prolongation and Torsade de Pointes safety concerns including removing citalopram in patients with congenital long QT syndrome as a contraindication and revised drug dosage and usage recommendations. You also agreed via email on March 23, 2012 to our minor modifications to the CYP2C19 section of the label.

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(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 Bill Bender, Senior Regulatory Project Manager, at (301) 796-2145.

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 (package insert and Medication Guide)

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
03/27/2012