



NDA 20822/S-043  
NDA 21046/S-020  
NDA 21323/S-040  
NDA 21365/S-030

**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 Applications (sNDA) dated April 2, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Celexa (citalopram hydrobromide) 10 mg, 20 mg, and 40 mg tablets (NDA 20822), Celexa (citalopram hydrobromide) 10 mg/5 ml oral solution (NDA 21046), Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 20 mg Tablets (NDA 21323), and Lexapro (escitalopram oxalate) 5 mg/5 ml Oral Solution (NDA 21365).

We acknowledge receipt of your amendments dated August 6, 2012, and September 14, 2012.

These "Prior Approval" supplemental new drug applications provide for class labeling revisions to the **Contraindications, Dosage And Administration, Warnings and Precautions, Drug Interactions, Use in Specific Populations, Patient Counseling Information, & Medication Guide** regarding serotonin toxicity associated with the co-administration of linezolid and methylene blue as well as revisions related to persistent pulmonary hypertension of the newborn as requested in Agency supplement request letters dated March 2, and 5, 2012.

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 and with the minor editorial revisions agreed upon in an email communication dated November 30, 2012, between you and Paul David, of this Agency.

**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, except with the revisions agreed upon in the September 24, 2012 communication, the enclosed labeling (text for the package insert, and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (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}*

Mitchell V. Mathis, M.D.  
CAPT, USPHS  
Director (acting)  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MITCHELL V Mathis  
12/03/2012