



NDA 20-822/S-027
NDA 21-046/S-007
NDA 21-323/S-015
NDA 21-365/S-008

Forest Laboratories, Inc.
Attention: Andrew Friedman, PharmD
Manager, Regulatory Affairs
Harborside Financial Center
Plaza Three, Suite 602
Jersey City, NJ 07311

Dear Dr. Friedman:

We acknowledge receipt of your supplemental new drug applications dated April 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celexa (citalopram hydrobromide) 10 mg, 20 mg and 40 mg Tablets (20-822), Celexa (citalopram hydrobromide) 10 mg/5 ml Oral Solution (21-046), Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 15 mg Tablets, and Lexapro (escitalopram oxalate) 5 mg/5 ml Oral Solution.

The above supplemental applications, submitted as "Changes Being Effected" submissions, provide for the following changes to product labeling as requested in our Agency letter dated March 19, 2004, and revised in an electronic communication to you from Paul David, of this office, on April 19, 2004:

1. The addition of a new subsection under **WARNINGS** entitled **Clinical Worsening and Suicide Risk**.
2. Revisions to the **PRECAUTIONS-Information for Patients** section.
3. Delete the section in **PRECAUTIONS-General** entitled "Suicide".
4. Add a reference to the **WARNINGS** section at the end of the **PRECAUTIONS- Pediatric Use** section, i.e., (see **WARNINGS-Clinical Worsening and Suicide Risk**).

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your labeling submitted on April 30, 2004. Accordingly, these supplemental applications are approved effective on the date of this letter.

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If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Thomas Laughren
5/20/04 08:46:09 AM
Signed for Russell Katz, M.D.