



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-822/S-023
NDA 21-046/S-005
NDA 21-323/S-003/S-007/S-010
NDA 21-365/S-001/S-004/S-005

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

Dear Mr. Friedman:

Please refer to your supplemental new drug applications dated June 6, received June 9, 2003 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/S-023), Celexa (citalopram hydrobromide) 10 mg/5 ml Oral Solution (21-046/S-005), Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 15 mg Tablets (21-323/S-010), and Lexapro (escitalopram oxalate) 5 mg/5 ml Oral Solution (21-365/S-005).

We acknowledge receipt of your submissions dated January 9, 2004, to supplemental applications 20-822/S-023 and 21-046/S-005.

These submissions constituted a complete response to our December 9, 2003 action letter.

We additionally acknowledge receipt of your submission dated January 20, 2004, providing for 20 copies of FPL as requested in our December 18, 2003, approval letter for supplemental applications 21-323/S-003/S-007 and 21-365/S-001/S-004.

Supplemental applications 20-822/S-023 and 21-046/S-005, submitted as "Changes Being Effected" supplements, provide for changes to the **WARNINGS**, **PRECAUTIONS**, and **DOSAGE AND ADMINISTRATION** sections to incorporate selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) class labeling changes in regards to bleeding related adverse events, discontinuation symptoms, and to adverse events occurring in neonates exposed to any of the SSRIs or SNRIs late in the third trimester.

We have completed the review of your resubmissions, 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 January 9, 2004 labeling. Accordingly, these applications are approved effective on the date of this letter.

We have also reviewed your final printed labeling submitted on January 20, 2004, and it is acceptable. Therefore, this labeling will be retained in our files.

Additionally, since our approval letter dated December 18, 2003, supercedes the labeling revisions proposed in supplemental applications 21-323/S-010 and 21-365/S-005, we are going to administratively close these supplements and retain them in our files.

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 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/

Russell Katz

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