DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 20-822/S-029, 21-046/S-009, 21-323/S-020, & 21-365/S-012

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

Dear Dr. Friedman:

Please refer to your supplemental new drug applications dated November 12, 2004, and received November 15, 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.

We additionally refer to an Agency approvable letter dated January 12, 2005 as well as a letter dated January 26, 2005 clarifying our requested revisions to the labeling for the above supplemental applications.

We acknowledge receipt of your submissions dated February 4, 2005, providing for a complete response to our January 12, and 26, 2005 Agency letters.

These supplements provide for the addition of a boxed warning and other changes to product labeling and the addition of a Medication Guide pertaining to pediatric suicidality.

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 the submitted final printed labeling (package insert submitted February 4, 2005), which incorporates all of the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

Since we have developed standardized labeling for all antidepressants used in children because of safety concerns associated with the use of these products in children, final printed labeling should be available on your WEB page within two weeks of the date of this letter, and on all products within 30 days. Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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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