



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-323/S-014

NDA 21-365/S-007

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 February 17, received February 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexapro (escitalopram oxalate) Tablets (NDA 21-323) and Lexapro (escitalopram oxalate) Oral Solution (NDA 21-365).

We additionally refer to an Agency approvable letter dated August 18, 2004 for the above supplemental applications.

We acknowledge receipt of your submission dated October 6, 2004, providing for a complete response to our August 18, 2004, Agency letter.

These supplements provide for revisions to labeling under the **ADVERSE EVENTS** section to delete the subsection entitled **Events Reported Subsequent to the Marketing of Citalopram**, and replace it with two new subsections entitled 1) **Events Reported Subsequent to the Marketing of Escitalopram**, and 2) **Events Reported Subsequent to the Marketing of Racemic Citalopram**.

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 October 6, 2004), which incorporates all of the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

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 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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