



NDA 21-323/S-003/S-007
NDA 21-365/S-001/S-004

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 November 26, 2002 (NDA 21-323/S-003 & 21-365/S-004), and February 6, 2003 (NDA 21-323/S-007 & 21-365/S-001), 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 acknowledge receipt of your submissions dated October 20, October 27, December 4, and December 11, 2003.

Your submission of October 20, 2003, constituted a complete response to our September 26, 2003 action letter for supplemental applications 21-323/S-003 & 21-365/S-004, and your submission of December 11, 2003, constituted a complete response to our November 25, 2003 action letter for supplemental applications 21-323/S-007 & 21-365/S-001.

These supplements provide for the following revisions to labeling:

Under supplemental applications 21-323/S-007 & 21-365/S-001: efficacy study reports from Studies 99001 & 99003 as additional trials supporting the efficacy of escitalopram in the treatment of major depressive disorder.

Under supplemental applications 21-323/S-003 & 21-365/S-004: treatment of generalized anxiety disorder.

We have completed the review of these applications, as amended, 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 enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

We note your agreement to the attached labeling in conference calls dated December 11, and 16, 2003, between the Agency and representatives from Forest.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements 21-323/S-003/S-007 & NDA 21-365/S-001/S-004." Approval of these submissions by FDA is not required before the labeling is used.

Additionally, we are requesting that you submit a "Prior Approval" supplemental new drug application to incorporate a new subsection under **ADVERSE REACTIONS** entitled **Events Reported Subsequent to the Marketing of Escitalopram**. This section should include all of the adverse events reported since marketing of escitalopram and not reported during the premarketing of escitalopram and the postmarketing of citalopram, i.e., these events would be postmarketing adverse events specific to escitalopram. This supplement should also contain the data to support your proposed additions to product labeling.

This supplement should be submitted within 60 days of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 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

Attachment

**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
12/18/03 09:31:43 AM