



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-323/S-030/S-031
NDA 21-365/S-021/S-022

Forest Laboratories, Inc.
Attention: Maricarmen Raposo
Senior Associate, Regulatory Affairs
Harborside Financial Center
Plaza Three, Suite 602
Jersey City, New Jersey 07311

Dear Ms. Raposo:

Please refer to your supplemental new drug applications dated May 22, 2008, received May 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 20 mg tablets (NDA 21-323) and Lexapro (escitalopram oxalate) 5 mg/ml Oral solution (NDA 21-365).

We acknowledge receipt of your submissions dated August 13, 2008, September 19, 2008, September 26, 2008, October 2, 2008, December 4, 2008, December 11, 2008, December 19, 2008, December 24, 2008, January 15, 2009, February 6, 2009, February 9, 2009, February 23, 2009, and March 6, 2009.

These supplemental new drug applications provide for the use of Lexapro (escitalopram oxalate) tablets and solution for the acute and maintenance treatment of adolescent major depressive disorder (MDD).

We have completed our review of your submissions as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling, unless we notify you otherwise.

CONTENT OF LABELING: STRUCTURED PRODUCT LABELING [SPL]

The final printed labeling (FPL) must be identical to the enclosed labeling [package insert and Medication Guide], and must be formatted in accordance with the requirements of 21 CFR 201.66.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured Product Labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the enclosed agreed-upon labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA labeling under NDAs 21-323/S-030/S-031 & 21-365/S-021/S-022".

POSTMARKETING COMMITMENT

We remind you of your following postmarketing commitment agreed upon in your submission dated February 23, 2009. This commitment is listed below.

1. Long-Term Safety Study

An open-label, 24-week safety study with escitalopram in children ages 7-11 .

PROTOCOL SUBMISSION: 14 months from the date of this letter

STUDY INITIATION: 18 months from the date of this letter

FINAL REPORT SUBMISSION: 5 years from the date of this letter.

Reference is also made to a teleconference between Forest and the Agency on March 10, 2009, regarding our suggestion that Forest conduct, as a Phase 4 Postmarketing Commitment, a 6 week double blind randomized safety and efficacy study in children ages 7-11 with Lexapro. This would be in addition to your proposed open label longer-term safety study in children. While we acknowledge your reluctance to conduct the 6 week efficacy study, we hope you will reconsider, since we feel this would be a benefit to the public health. As you know, Lexapro is already being used to treat MDD in children, and such use is likely to increase with the approval of a claim for MDD in adolescents.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled “**Postmarketing Study Commitment Protocol**”, “**Postmarketing Study Commitment Final Report**”, or “**Postmarketing Study Commitment Correspondence.**”

LETTERS TO HEALTH CARE PROFESSIONALS

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

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

INTRODUCTORY PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this indication. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research

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Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

REPORTING REQUIREMENTS

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 LCDR Renmeet Grewal, Pharm.D., Senior Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.

Director

Division of Psychiatry Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

Enclosure: Product Labeling & Medication Guide