DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-323

Forest Laboratories, Inc.
Attention: Robert W. Ashworth, Ph.D.
Senior Director, Regulatory Affairs
Plaza 3, Suite 602
Harborside Financial Center
Jersey City, NJ 07311

Dear Dr. Ashworth:

Please refer to your new drug application (NDA) dated March 23, 2001, received March 23, 2001, 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.

We acknowledge receipt of your submission dated February 28, 2002. Your submission of February 28, 2002 constituted a complete response to our January 23, 2002 action letter.

This new drug application provides for the use of Lexapro for the treatment of major depressive disorder.

We have completed the review of this application, 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, the application is approved effective on the date of this letter.

We note your agreement to the attached labeling in an e-mail communication dated August 14, 2002.

Additionally, we note your agreement, conveyed in your February 28, 2002 resubmission, to adopt the following dissolution method and specification for all strengths of the Lexapro (escitalopram oxalate) 5 mg, 10 mg, and 20 mg Tablets:

Apparatus:	USP Apparatus 2 (Paddle)
Paddle Speed:	50 RPM
Medium:	900 mL 0.1N HCL at 37^{o}C
Specification:	NLT (b)(in 30 minutes

We also refer to your fax transmission on August 5, 2002, in which you provided additional ECG information for escitalopram. In particular, we reference your analysis of plasma concentration and change from baseline in QTc interval in study MD-01. We ask that you provide, postapproval, a more complete report on your analysis, including a listing of individual plasma concentrations and the corresponding values for change from baseline in

QTc interval.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-323." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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

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