



NDA 21-427 S-030

**NDA APPROVAL**

Lilly Research Laboratories  
Attention: Peter Robins, M.SC., Ph.D  
Associate Director, U.S. Regulatory Affairs  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Dr. Robins:

Please refer to your new drug application (NDA) dated January 30, 2009, received February 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cymbalta (duloxetine hydrochloride) 20 mg, 30 mg, 40 mg, and 60 mg capsules.

We acknowledge receipt of your submissions dated May 29, 2009, August 26, 2009, August 31, 2009, and October 6, 2009.

This new drug application provides for the use of Cymbalta, 20 mg, 30 mg, 40 mg and 60 mg tablets for the maintenance of Generalized Anxiety Disorder (GAD).

We have completed our review of the application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

### **CONTENT OF LABELING**

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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide. For administrative purposes, please designate this submission, “**SPL for approved NDA 21-427.**”

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. The sponsor is currently studying this drug in acute pediatric studies and this is considered sufficient. Therefore, the sponsor is not required to perform maintenance studies in the pediatric population since it is often difficult to perform long-term studies within this age group.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
5600 Fishers Lane  
Rockville, MD 20857

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original

NDA 21-427 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call CDR Sue Larkin, Regulatory Project Manager, at (301) 796-4796.

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21427	SUPPL-30	ELI LILLY AND CO	CYMBALTA(DULOXETINE HCL)20,30,40,60MG

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

/s/

THOMAS P LAUGHREN  
11/19/2009