



NDA 21-427/S-029

Eli Lilly and Company  
Attention: Bryan Boggs, Pharm.D.  
Associate Director, Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Dr. Boggs:

Please refer to your supplemental new drug application dated December 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cymbalta (duloxetine hydrochloride) Delayed-Release Capsules 20, 30 and 60 mg.

Reference is also made to an FDA letter dated December 4, 2008, notifying you, under section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Cymbalta. This information pertains to the risk of neuroleptic malignant syndrome associated with use of selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs), including Cymbalta.

We have completed our review of this supplemental application. The application 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/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling. 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 supplement NDA 21-427/S-029.”**

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

**LETTERS TO HEALTH CARE PROFESSIONALS**

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  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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

Sincerely,

*{See appended electronic signature page}*

Thomas Laughren, M.D.  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Thomas Laughren  
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