DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-427/S-021/S-027/S-028

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

Dear Dr. Boggs:

We acknowledge receipt of your supplemental new drug applications dated October 25, 2007 (S-021), August 11, 2008 (S-027), and December 5, 2008 (S-028), 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.

We additionally acknowledge receipt of your amendments dated March 10, 2009.

These supplemental new drug applications propose the following revisions to product labeling:

S-021
- Revisions to Section 5.6 related to discontinuation effects
- Revisions to Section 6.11 related to premarketing and postmarketing reports

S-027
- Revisions to section 6.12 (Postmarketing Spontaneous Reports)

S-028
- Revisions to section 6.12 (Postmarketing Reports) & addition of toll free number to the Medication Guide

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

Within 21 days of the date of this letter, submit 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 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 supplements 21-427/S-021/S-027/S-028."

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

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., Senior 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

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

/s/

Thomas Laughren
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