DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-411/S-024/S-025/S-026

Eli Lilly and Company
Attention: Roland Usher, M.S.
Associate Director
US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Usher:

Please refer to your supplemental new drug applications dated September 26, 2007 (S-024), November 21, 2007 (S-025) and November 29, 2007 (S-026), received September 27, 2007, November 21, 2007 and November 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera® (atomoxetine hydrochloride) Capsules.

We acknowledge receipt of your submissions dated October 18, 2007; October 19, 2007; November 21, 2007; November 29, 2007; December 10, 2007; December 13, 2007; January 18, 2008; February 13, 2008; March 12, 2008; March 28, 2008; and May 28, 2008.

These supplemental new drug applications provide for the use of Strattera® (atomoxetine hydrochloride) Capsules in patients with attention-deficit hyperactivity disorder (ADHD) and comorbid anxiety disorder without causing worsening of anxiety.

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

The final printed labeling (FPL) must be identical to the enclosed labeling and Medication Guide.

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "FPL for approved supplement NDA 21-411 S-024, S-025 and S-026." Approval of these submissions by FDA is not required before the labeling is used.

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

Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Nicholette Hemingway, Regulatory Project Manager, at (301) 796-1365.

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 (Labeling and Medication Guide)

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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