DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021411/S-039

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Roland W. Usher
Director, Global Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Usher:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Strattera (atomoxetine hydrochloride) 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg capsules.

This "Changes Being Effected" supplemental new drug application proposes to update the label to reflect findings from a Cardiovascular Safety Report (eCTD sequence 0051) submitted on August 15, 2011, entitled "Analysis of the Changes in Hemodynamic Parameters of Blood Pressure and Heart Rate Associated with Atomoxetine Treatment in Pediatric and Adult Patients with ADHD in Clinical Trials and in Healthy Adult Subjects who are CYP-2D6 Poor Metabolizers". Updates were made to Sections: Highlights, 4.5 Severe Cardiovascular Disorders [Contraindications], 5.4 Effects on Blood Pressure and Heart Rate [Warnings and Precautions], 6.1 Clinical Trials Experience [Adverse Reactions], and 6.2 Postmarketing Spontaneous Reports [Adverse Reactions].

We have completed our review of this supplemental application, as amended in emails exchanged on June 11, 2012 and June 13, 2012. 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide) as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

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:
Content of Labeling

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
06/14/2012