DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-411/S-004/S-012/S-013/S-015/S-021

Eli Lilly and Company
Attention: Mark S. Leusch, Ph.D.
Associate Director, Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Leusch:

Please refer to your supplemental new drug applications dated November 20, 2004 (S-004), April 20, 2005 (S-012), October 19, 2005 (S-013), and January 27, 2006 (S-015) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera (atomoxetine HCl) Capsules.

Additionally, we acknowledge receipt of your supplemental new drug application dated April 9, 2007 (S-021).

We also refer to Agency letters dated July 21, 2004, May 30, 2006, June 8, 2006, October 2, 2006, and February 21, 2007.

Your submissions dated December 20, 2006 (S-004), October 30, 2006 (S-012), and December 20, 2006 (S-013 & S-015) constituted a complete response to our action letters dated October 2, 2006 (S-004, S-013, & S-015), and June 8, 2006 (S-012).

These supplements, submitted under "Changes Being Effected", provide for the following revisions to labeling:

S-004

- Revisions to the **OVERDOSAGE** section.

S-012

1. The addition of a new subsection entitled Aggressive Behavior or Hostility to the **PRECAUTIONS-General** section.
2. Additions to the **PRECAUTIONS**-Information for Patients section.
3. Additions to the Medication Guide under the section entitled “Other important safety information about Strattera.

S-013

1. Addition to the **PRECAUTIONS - Information for Patients** section to denote that Strattera is an occular irritant, and the capsules should not be opened.
2. Addition to the **DOSING AND ADMINISTRATION - Instructions for Use/Handling** section that Strattera capsules should not be opened.

3. The addition of a new section under **ADVERSE REACTIONS** entitled **Postmarketing Spontaneous Reports** as well as a subsection entitled *Vascular Disorders*
4. Revisions to the Medication Guide to reflect that Strattera is an occular irritant.

S-015

- The addition of a new subsection under **ADVERSE REACTIONS – Postmarketing Spontaneous Reports** entitled *Cardiovascular System* with the terms "QT prolongation" and "syncope" added to this subsection.
- Revisions to the **PRECAUTIONS**-General-Effects on Blood Pressure and Heart Rate.
- Addition of a new subsection entitled Peripheral Vascular Disease under the **PRECAUTIONS**-General section.
- Addition of a new subsection entitled Priapism under the **PRECAUTIONS**-General section.
- Addition of a new subsection entitled Seizures under the **ADVERSE REACTIONS** and **Postmarketing Spontaneous Reports** sections.

S-021

- Revisions to the Medication Guide regarding cardiovascular and psychiatric risks.

We have completed the review of these applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LT Felecia Curtis, Regulatory Project Manager, at 301-796-1074.

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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