



NDA 21-411/S-005

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 application dated November 14, 2007, received November 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera (atomoxetine HCl) Capsules.

We acknowledge receipt of your submission dated January 8, 2008.

Your submission of November 14, 2007 constituted a complete response to our April 20, 2007 action letter.

This supplemental new drug application provides for the use of Strattera (atomoxetine hydrochloride) Capsules for maintenance treatment of attention-deficit hyperactivity disorder (ADHD) in children and adolescents.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and in the enclosed labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling. These revisions are terms of the approval of this application.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Nicholette Hemingway, Regulatory Project Manager, at (301) 796-1365.

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 (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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