DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-411 / S-018

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 October 4, 2006, received October 5, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera (atomoxetine HCl) Capsules.

This "Changes Being Effected" supplemental new drug application provides for CNS stimulant class labeling revisions to strengthen the WARNINGS section with regard to serious cardiovascular events and psychiatric events as requested in our letter of June 21, 2006.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 4, 2006 (copy attached).

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 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, RN, Regulatory Project Manager, at (301) 796-0877.

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

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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