DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-411/S-002 & 011

Eli Lilly and Company
Attention: David Clarke, Ph.D., D.A.B.T.
Regulatory Research Scientist
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Clarke:

We acknowledge receipt of your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	Drug Name	Submission Date	Receipt Date	Provides For:
NDA 21-411/S-002	Strattera (atomoxetine HCL) Capsules	December 23, 2002	December 24, 2002	Revisions to the PRECAUTIONS, Drug-Drug Interaction-Albuterol section of labeling.
NDA 21-411/S-011	Strattera (atomoxetine HCL) Capsules	December 17, 2004	December 20, 2004	Revisions to the WARNINGS section of the package insert and to the patient package insert to include hepatic safety information.

Additionally, we acknowledge receipt of your submission dated December 17, 2004 that provided a complete response to the Agency's action letter dated July 21, 2004 for supplement # 002.

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

In addition, please refer to the Agency's action letter dated July 21, 2004 for your Changes Being Effected supplemental new drug application (S-004) submitted on November 20, 2003 for Strattera. This supplement provided for revisions to the OVERDOSE section of labeling to include two new subsections entitled, "Human Experience" and "Management of Overdose". We note that you provided a response to the Agency's action letter on December 17, 2004. Although the changes submitted in S-004 have been incorporated into product labeling, your response is currently under review.

The final printed labeling (FPL) must be identical to the agreed upon changes made in your submissions dated December 17, 2004 for S-002 and S-011. Marketing the product with FPL that is

not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-411/S-002 and S-011**." Approval of this submission by FDA is not required before the labeling is used.

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 Richardae Taylor, Pharm.D., Regulatory Project Manager, at (301) 594-5793.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Russell Katz
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