DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 21-411

Eli Lilly and Company
Attention: Robin P. Wojcieszek, R.Ph.
Senior Regulatory Scientist
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms.Wojcieszek:

Please refer to your supplemental new drug application (NDA) dated December 11, 2002, received December 13, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera™ (atomoxetine hydrochloride) Capsules.

This supplemental new drug application provides for a patient package insert (PPI) as part of the labeling.

We refer to two facsimile communications dated December 13 and December 18, 2002, concerning the wording of the PPI labeling.

We also refer to the January 16, 2003, telephone conversation between Ms. Robin Wojcieszek, Lilly Senior Regulatory Scientist, and Ms. Anna Marie H. Weikel, Senior Project Manager of this Division, during which the final PPI labeling was agreed upon.

We have completed the review of this supplemental application, 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 agreed upon enclosed PPI labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the agreed upon enclosed labeling (text for the patient package insert). 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 the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-411/S-001." Approval of this submission by FDA is not required before the labeling is used.

If you should have any questions, please call Ms. Anna Marie H. Weikel, R.Ph., Senior Regulatory Project Manager, at (301) 594-5535.

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

Enclosure

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
1/17/03 08:17:30 AM