DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-411/SCS-010

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:

Please refer to your supplemental new drug application dated October 20, 2004, received October 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Strattera (atomoxetine hydrochloride) Capsules.

We acknowledge receipt of your additional submission dated December 3, 2004.

This supplemental new drug application provides for two higher strengths of Strattera capsules, 80 mg and 100 mg.

We have 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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, patient package insert, and immediate container and carton labels) on October 20, 2004. This labeling should also reflect any additional labeling changes that have been approved since your October 20, 2004 submission.

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 this submission "**FPL for approved supplement NDA 21-411/S-010**." Approval of this submission by FDA is not required before the labeling is used.

Chemistry Manufacturing and Controls
A 24 month expiry has been granted for the 80 mg and 100 mg strengths of Strattera in (b)(4) bottles.

Promotional Materials
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to

this division/ the Division of Neuropharmacological Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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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