



NDA 21-411/S-029/S-030

Eli Lilly and Company
Attention: Roland Usher, M.S.
Associate Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Usher:

Please refer to your supplemental new drug applications dated September 30, 2008 (S-029), and December 10, 2008 (S-030), submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Strattera (atomoxetine hydrochloride) 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg capsules.

Reference is also made to the letter from the Agency dated November 7, 2008, requesting labeling revisions to Sections 5.2 and 17.3 pertaining to severe liver injury, and your email communication dated April 28, 2009 regarding the above referenced supplemental NDA.

These supplemental new drug applications provide for the following changes to product labeling:

S-029

- Revisions to Sections 5.4 (Warnings and Precautions/Effects on Blood Pressure and Heart Rate) and 6.2 (Postmarketing Spontaneous Reports).

S-030

- Revisions to Highlights (Warnings and Precautions/Severe Liver Injury), Section 5.2 (Warnings and Precautions/Severe Liver Injury) and 17.3 (Patient Counseling Information/Severe Liver Injury).

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert and Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-411/S-029/S-030."

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
Suite 12B05
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, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

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: Product Labeling & 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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