NDA 021411/S-053

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: U.S. Agent Brandon Lane
Director, Global Regulatory Affairs
Drop Code 2543
Indianapolis, IN 46285

Dear Brandon Lane:

Please refer to your supplemental new drug application (sNDA) dated and received March 12, 2026, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Strattera (atomoxetine) capsules.

This prior approval sNDA provides for the following revisions to the Prescribing Information:

- Changes to be consistent with FDA guidance (e.g., removed clinical data from the BOXED WARNING and the DOSAGE AND ADMINISTRATION (D&A) sections, removed clinical practice information and clarified the approved age groups in the INDICATIONS AND USAGE section).

- Reorganized information to improve clarity (e.g., reorganized dosage information into subsections in the D&A section, placed the directives to health care providers before the description of clinically significant risks in the WARNINGS AND PRECAUTIONS section, placed the common adverse reactions (AR) prior to the AR of interest in the ADVERSE REACTIONS section, moved clinically significant drug interaction information from the text to a table in the DRUG INTERACTIONS section, moved information about safety studies from the USE IN SPECIFIC POPULATIONS to the CLINICAL STUDIES section, moved pharmacokinetic information from the text to a table in the *Pharmacokinetics* subsection).

- Clarified the recommendations for use of STRATTERA in CYP2D6 poor metabolizers and in patients taking concomitant strong CYP2D6 inhibitors.

- Moved insignificant drug interaction information from the DRUG INTERACTIONS section to the *Pharmacokinetics* subsection.

- Ensured that the *Pediatric Use* and *Geriatric Use* subsections included required pediatric use and geriatric use regulatory statements, respectively.

Changes to the Medication Guide were made to be consistent with changes to the Prescribing Information and with the Medication Guide regulations as per 21 CFR 208.20.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

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, contact Jenna Kim, Regulatory Project Manager, at jiye.kim@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tiffany R Farchione, MD
Director
Division of Psychiatry
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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