



NDA 020822/S-051
NDA 021323/S-051
NDA 021365/S-036

SUPPLEMENT APPROVAL

Allergan Sales, LLC
Attention: Nadia C. Success
Senior Manager, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Success:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received October 19, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Celexa (citalopram) 10 mg, 20 mg, and 40 mg tablets (NDA 020822); Lexapro (escitalopram) 5 mg, 10 mg, and 20 mg tablets (NDA 021323); Lexapro (escitalopram) oral solution equivalent to 1 mg/ml escitalopram base (NDA 021365).

These "Changes Being Effected" supplemental new drug applications provide for revisions to the content of prescribing information and carton and container labeling to align the established names of Celexa tablets, Lexapro tablets, and Lexapro solution with the USP monographs for each product. NDA 021323/S-051 and NDA 021365/S-036 also provide for revisions to the Medication Guide as requested in our Changes Being Effected Supplement Request letter dated September 21, 2018.

APPROVAL & LABELING

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

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted, under NDAs 021323 and 021365, a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. 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 titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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).

CARTON AND CONTAINER LABELING

We acknowledge your October 19, 2018, submission containing final printed carton and container labeling.

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 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 application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, please email Simran Parihar, PharmD, at simran.parihar@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, MD
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:

Content of Labeling
Prescribing Information
Medication Guide
Carton and Container Labeling

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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01/11/2019 04:12:13 PM
On behalf of Mitch Mathis