NDA 219131/S-001

APPROVAL LETTER

Almatica Pharma LLC
Attention: Angela Turner
Senior Director, Regulatory Affairs
44 Whippany Road
Suite 300
Morristown, NJ 07960

Dear Angela Turner:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 4, 2026, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Duloxetine Delayed-Release Capsules.

This “Changes Being Effected” supplemental new drug application provides for revisions to the current approved 80 mg, 90 mg, and 120 mg container labeling to update the Medication Guide dispensing statement from "PHARMACIST: Dispense the accompanying Medication Guide to each patient." to "PHARMACIST: Dispense the Medication Guide provided separately to each patient."

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELS

We acknowledge your March 4, 2026, submission containing final printed carton and container labeling.

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).

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.[2]

If you have any questions, call Stephanie Ngan, Regulatory Business Process Manager, at (240) 402 - 5932.

Sincerely,

{See appended electronic signature page}

Joyce Crich, Ph.D.
Unit Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality

Enclosure:
Carton and Container Labeling

Joyce Crich

Digitally signed by Joyce Crich
Date: 8/17/2026 01:01:02PM
GUID: 5058dd5000000681be093e8cc380aa3f