NDA 215401/S-016

SUPPLEMENT APPROVAL

Noven Pharmaceuticals, Inc.
Attention: Sandra Updegrove
Director, Regulatory Affairs
100 Town Square Place
Jersey City, NJ 07310

Dear Sandra Updegrove:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 12, 2026, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xelstrym (dextroamphetamine) transdermal system.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

1. Update the carton QR code (currently links to the Mindful Patch APP) and link the QR code to the "Toole and Resources" section on the Xelstrym patient website: https://www.xelstrym.com/#tools-resources .
2. Update the text next to the carton QR code to be the following: "Additional resources available by scanning the QR code" (Replacing Current Text: "Optional digital tools and resources available on the app by scanning the QR code").

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 January 12, 2026, submission containing final printed carton.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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).

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

Sincerely,

{See appended electronic signature page}

Julia Pinto, Ph.D.
Supervisor, Division of Product Quality Assessment VIII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton Labeling

Andrei Ponta

Digitally signed by Andrei Ponta
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