DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21514/S-023

SUPPLEMENT APPROVAL

Noven Pharmaceuticals, Inc.
Attention: Kanan Solanki, PharmD
Associate Director, Regulatory Affairs
Empire State Building, 350 Fifth Avenue, 37thFloor
New York, NY 10118

Dear Dr. Solanki:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 22, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Daytrana (methylphenidate transdermal system) 10mg/9 hours (1.1 mg/hr), 15mg/9 hours (1.6 mg/hr), 20mg/9 hours (2.2 mg/hr), and 30mg/9 hours (3.3 mg/hr).

We also refer to our letter dated June 23, 2015, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Daytrana (methylphenidate transdermal system). This information pertains to the risk of chemical leukoderma.

This supplemental new drug application provides for the addition of new subsection under WARNINGS AND PRECAUTIONS entitled "Chemical Leukoderma", addition of new subsection under PATIENT COUNSELING INFORMATION – Information for Patients entitled "Chemical Leukoderma" , and revisions to the Medication Guide relating to chemical leukoderma to the labeling for Daytrana (methylphenidate transdermal system) consistent with our June 23, 2015 letter.

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 text.

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 package insert, 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 includes 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

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 Shin-Ye Sandy Chang, Regulatory Project Manager, at (301) 796-3971, or email shinye.chang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
08/14/2015