DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021299/S-027/S-028/S-029

SUPPLEMENT APPROVAL

Noven Therapeutics, LLC
Attention: Amaury Sanchez
Sr. Manager Regulatory Affairs
11960 SW 144 Street
Miami, FL 33186

Dear Ms. Sanchez:

Please refer to your Supplemental New Drug Applications (sNDA) 021299/S-027 and S-028, dated March 19, 2012 and received March 20, 2012, and sNDA 021299S/-029, dated May 25, 2012 and received May 29, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pexeva (paroxetine mesylate) 10mg, 20mg, 30mg, 40mg tablets.

We acknowledge receipt of your amendment dated July 13, 2012 and received July 16, 2012 for S-027.

These "Prior Approval" supplemental new drug applications provide for:

- **S-027:** Class labeling language regarding serotonin toxicity associated with the co-administration of linezolid and methylene blue as requested in the March 5, 2012 Supplement Request Letter, which was further revised on July 6, 2012 and on September 5, 2012.
- **S-028:** Class labeling language to the Pregnancy-Nonteratogenic Effects section related to persistent pulmonary hypertension of the newborn as requested in the March 2, 2012 Supplement Request Letter, which was further revised on September 5, 2012.
- **S-029:** Labeling updates to incorporate safety changes to be consistent with other approved paroxetine products.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text and with the minor editorial revisions agreed upon in an email communication dated September 27, December 4, and December 7, 2012, between you and Juliette Touré, of this Agency.

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 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 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, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
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
12/18/2012