DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-299/S-021

AAC/Kendle Consulting
Attention: Anthony C. Celeste
Senior Vice President
7361 Calhoun Place, Suite 500
Rockville, MD 20855-2765

Dear Mr. Celeste:

We acknowledge receipt of your supplemental new drug application dated and received January 18, 2008, submitted pursuant to section 505(b)(2)of the Federal Food, Drug, and Cosmetic Act for Pexeva (paroxetine mesylate) tablets.

Reference is also made to an Agency letter dated January 3, 2008, requesting class labeling revisions to your product labeling related to abnormal bleeding.

This supplement, submitted as a "Changes Being Effected" application, provides for revisions to the **Precautions** section regarding abnormal bleeding as requested by the Agency in our letter dated January 3, 2008. Additionally, we note that you have incorporated our changes, verbatim.

We completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the revisions noted above.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that incorporates the same revisions submitted on January 18, 2008, and enclosed to this letter. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission “SPL for approved supplement NDA 21-299/S-021.”

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LCDR Renmeet Grewal, Senior Regulatory Project Manager, at 301-796-1080.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Mitchell Mathis
3/6/2008 08:09:20 AM
For Dr. Laughren