DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-299/S-019

AAC/Kendle Consulting
Attention: Anthony Celeste
Senior Vice President
Kendle Regulatory Affairs
7361 Calhoun Place, Suite 500
Rockville, Md 20855

Dear Mr. Celeste:

We acknowledge receipt of your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pexeva (paroxetine mesylate), dated May 18, 2007 and amended on June 12, 2007 and July 2, 2007.

We additionally refer to an Agency letter dated May 1, 2007, requesting revisions to your prescriber labeling and Medication Guide based upon the December 13, 2006 meeting of the Psychopharmacologic Drugs and Advisory Committee.

Reference is also made to an e-mail communication from the Agency dated June 21, 2007, requesting additional revisions to the labeling, and your e-mail dated June 26, 2007 accepting these changes.

This supplemental new drug application, submitted under "Changes Being Effected" provides for the following revisions to labeling:

1. Revisions to the Black Box entitled **Suicidality and Antidepressant Drugs** at the beginning of the prescriber labeling.
2. Revisions to the **WARNINGS-Clinical Worsening and Suicide Risk** section.
3. Revisions to the **PRECAUTIONS-Information for Patients** section.
4. Revisions to the **MEDICATION GUIDE**.

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

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 is identical in content to the enclosed labeling text. 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 supplements 21-299/S-019." We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany

any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

In addition, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant new risk information relating to your drug product. We are hereby requesting that all promotional materials for your drug product that include representations about your drug product be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important new information described in the **WARNINGS** and **PRECAUTIONS** sections that appear in the revised package labeling. Please submit a written response to this request 14 days from the date of this letter stating whether you intend to comply with this request, to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications by facsimile at (301)796-9878 or at 5901-B Ammendale Road, Beltsville, MD 20705.

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 Renmeet Grewal, Pharm. D., Regulatory Project Manager, at (301) 796-1080 or Bill Bender, Regulatory Project Manager, at 301-796-2145.

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

Enclosure

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

/s/

Thomas Laughren
8/3/2007 09:20:44 AM