DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-299/(b)(4) S-017/(b)(4)

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

Dear Mr. Celeste:

Please refer to your supplemental new drug application dated and received March 13, 2006 (NDA 21-299/S-017), submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Pexeva (paroxetine mesylate) 10 mg, 20 mg, 30 mg, and 40 mg Tablets.

We acknowledge receipt of your amendments dated April 20, June 6, September 29, October 11, and October 12, 2006.

This supplemental new drug application provides for the use of Pexeva (paroxetine mesylate) Tablets for Generalized Anxiety Disorder.

We have completed the review of your submission, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling. Accordingly, this application is approved effective on the date of this letter.

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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Additionally, since this labeling incorporates the changes proposed in supplemental applications (b)(4) (b)(4), we are going to administratively close these supplements and retain them in our files.

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 concerning this supplemental application, call Paul David, R.Ph., Chief Project Management Staff, at (301) 796-1058.

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
12/9/2006 03:32:26 PM