DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-299 / S-020

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 August 22, 2007, received August 23, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pexeva (paroxetine mesylate) tablets.

This "Changes Being Effected" supplement provides for labeling changes pertaining to hyponatremia under the PRECAUTIONS and Geriatric Use subsections as requested in our letter of August 7, 2007, as follows:

PRECAUTIONS

Hyponatremia: Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including PEXEVA® (paroxetine mesylate). In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Cases with serum sodium lower than 110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume depleted may be at greater risk (see Geriatric Use). Discontinuation of PEXEVA® (paroxetine mesylate) should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted.

Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death.

Geriatric Use

SSRIs and SNRIs, including PEXEVA® (paroxetine mesylate), have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event (See PRECAUTIONS, Hyponatremia).

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 23, 2007 (copy attached).

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

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, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@FDA.HHS.GOV.

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/

Thomas Laughren
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