DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-860/S-001

Warner Chilcott
Attention: Ileana Brown
Director, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Ms. Brown:

Please refer to your supplemental new drug application dated October 5, 2006, received October 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SARAFEM® (fluoxetine hydrochloride tablets).

We also refer to your communication of March 22, 2007, wherein you agreed to the Division's proposed labeling changes.

This "Changes Being Effected" supplemental new drug application provides for the addition of language pertaining to serotonin syndrome with concomitant use of selective serotonin reuptake inhibitors (SSRIs)/selective norepinephrine reuptake inhibitors (SNRIs) and 5-hydroxytryptamine receptor agonists (triptans), increased risk for persistent pulmonary hypertension in newborns following exposure to SSRIs, and relapse of major depression in women who discontinue antidepressant medication during pregnancy.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the 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 that agreed to in your March 22, 2007 submission. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-860/S-001**." Approval of this submission by FDA is not required before the labeling is used.

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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic Products
Office of New Drugs III
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/

Scott Monroe
4/5/2007 12:25:49 PM