DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-860/S-002

Warner Chilcott Company, Inc.
Attention: Deepa D. Desai, M.S.
Senior Manager, Regulatory Affairs
100 Enterprise Drive
Rockaway, New Jersey 07866

Dear Ms. Desai:

Please refer to your supplemental new drug application dated May 31, 2007, received June 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SARAFEM® (fluoxetine hydrochloride tablets).

We acknowledge receipt of your submissions dated August 6 and 24, 2007.

This "Changes Being Effected" supplemental new drug application provides for revisions to the labeling to include information requested in the letter issued to you dated May 1, 2007, and additional requests made by us based upon further recommendations by the Division of Psychiatry Products for class labeling of antidepressant products.

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

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

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office Of Drug Evaluation III
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/

Scott Monroe

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