DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-860

Warner Chilcott Company, Inc.
Attention: Alvin Howard
Vice President, Regulatory Affairs
100 Enterprise Drive
Rockaway, NJ 07866

Dear Mr. Howard:

Please refer to your new drug application (NDA) dated May 19, 2005, received May 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sarafem® (fluoxetine hydrochloride) Tablets.

We also acknowledge receipt of your submissions dated July 14, August 30, September 12, 15, October 31, December 2, 2005, and January 26, February 2, 20, 24, March 1, 3, 20(2), 22, 27, April 3, May 3, and May 18, 2006.

The March 22, 2006, submission constituted a complete response to our March 20, 2006, action letter.

This new drug application provides for the use of Sarafem® (fluoxetine hydrochloride) Tablets for the treatment of premenstrual dysphoric disorder.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and Medication Guide submitted on May 18, 2006) and immediate container and carton labels submitted May 3, 2006. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-860**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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) 796-0933.

Sincerely,

*{See appended electronic signature page}*

Scott Monroe, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation and Research
Center for Drug Evaluation and Research

Enclosure

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

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/s/

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Scott Monroe

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