



NDA 20-936/S-013

GlaxoSmithKline
Attention: Matthew Whitman
One Franklin Place
PO Box 7929
Philadelphia, PA 19101-7929

Dear Mr. Whitman:

Please refer to your supplemental new drug application dated March 27, 2003, received March 27, 2003, which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil CR (paroxetine hydrochloride) Controlled-Release Tablets.

We also acknowledge receipt of your submissions dated June 23, 2003, July 2, 2003, November 14, 2003, and December 19, 2003, as well as your secure e-mail transmission of January 16, 2004.

This supplemental new drug application provides for the use of Paxil CR in the treatment of premenstrual dysphoric disorder (PMDD) using an intermittent dosing regimen.

Application Approved. 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 appended agreed-upon labeling text (package insert).

Final Printed Labeling. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Please submit the FPL electronically, 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 20-936/S-013”. Approval of this submission by FDA is not required before the labeling is used.

Deferral of Requirement for Pediatric Studies: Postmarketing Commitment Required. 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 deferring submission of your pediatric studies, for the use of Paxil CR to treat PMDD using an intermittent dosing regimen, in children aged 10 through 17 years, for five years from the date of this letter.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the use of Paxil CR to treat PMDD using an intermittent dosing regimen in pediatric patients ages 10 to 17 years.

Submit the final pediatric study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated “**required Pediatric Study Commitments.**”

Promotional Materials. 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 this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising and Communications (DDMAC), HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Healthcare Professional Letters. If you issue a letter communicating important information about this drug product (i.e., a “Dear Healthcare Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 contact Doris J. Bates, Ph.D., Regulatory Project Manager, at 301-594-2850, or via e-mail at batesd@cderr.fda.gov.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

attachment

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

/s/

Russell Katz
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