



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-031/S-042  
NDA 20-936/S-018

GlaxoSmithKline  
Attention: P. Kaia Agarwal, M.Sc.  
Senior Director, Psychiatry, U.S., Regulatory Affairs  
One Franklin Plaza, P.O. Box 7929  
Philadelphia, PA 19101

Dear Ms. Agarwal:

Please refer to your supplemental new drug applications dated March 16, received March 17, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil (paroxetine hydrochloride) Immediate Release Tablets (NDA 20-031), and Controlled Release Tablets (NDA 20-936).

Reference is also made to an Agency letter dated October 26, 2004, to the above applications.

We acknowledge receipt of your submissions dated December 8, 2004. Your submissions dated December 8, 2004, constituted a complete response to our October 26, 2004 letter.

These applications, submitted as "Changes Being Effected" supplements, provide for revisions to 1) the **CLINICAL PHARMACOLOGY** section, 2) **PRECAUTIONS-Drugs Metabolized by Cytochrome P450IID6** section to indicate that coadministration of paroxetine and risperidone or atomoxetine should be approached with caution and 3) various other places to revise the P450 nomenclature.

We have completed the review of your resubmission, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your December 8, 2004 labeling. Accordingly, these applications are approved effective on the date of this letter.

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, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

*{See appended electronic signature page}*

Thomas Laughren, M.D.  
Acting Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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/s/

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Thomas Laughren  
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