DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-031/S-043
NDA 20-936/S-019

Glaxo SmithKline
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:

We acknowledge receipt of your supplemental new drug applications dated April 28, 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).

The above supplemental applications, submitted as "Changes Being Effected" submissions, provide for the following changes to product labeling as requested in our Agency letter dated March 19, 2004, and revised in an electronic communication to you from Paul David, of this office, on April 19, 2004:

1. The addition of a new subsection under **WARNINGS** entitled **Clinical Worsening and Suicide Risk**.
2. Revisions to the **PRECAUTIONS-Information for Patients** section.
3. Delete the section in **PRECAUTIONS-General** entitled “Suicide”.
4. Add a reference to the **WARNINGS** section at the end of the **PRECAUTIONS- Pediatric Use** section, i.e., (see **WARNINGS-Clinical Worsening and Suicide Risk**).
5. The Paxil labeling includes a change under the **DOSAGE AND ADMINISTRATION/Special Populations: Treatment of Women During the Third Trimester** section. The adjective “Pregnant” has been added before the noun “Women” in the subsection title as requested in an Agency letter dated April 8, 2004.

We have completed the review of these supplemental applications 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 labeling submitted on April 28, 2004. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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

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

/s/

Thomas Laughren
5/21/04 08:48:16 AM