DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-031/S-039/S-040
NDA 20-936/S-015/S-016

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:

Please refer to your supplemental new drug applications dated June 16, 2003 (NDAs 20-031/S-039 & 20-936/S-015) and July 24, 2003 (NDAs 20-031/S-040 & 20-936/S-016) 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 Agency action letters dated December 16, 2003 to applications 20-031/S-039 and 20-936/S-015, and January 28, 2004 to applications 20-031/S-040 and 20-936/S-016.

We additionally refer to an Agency approval letter to the Paxil CR application, NDA 20-936/S-013, dated January 27, 2004.

We acknowledge receipt of your submissions to supplemental applications 20-031/S-039/S-040 and 20-936/S-015/S-016 dated March 5, and 8, 2004, respectively.

Your submissions dated March 5, and 8, 2004, constituted a complete response to our December 16, 2003, and January 28, 2004 action letters.

Supplemental applications, 20-031/S-039/S-040 and 20-936/S-015/S-016, provide for revisions to the **PRECAUTIONS-Abnormal Bleeding**, **PRECAUTIONS-Information for Patients**, **PRECAUTIONS-Drug Interactions**, and **PRECAUTIONS-General-Discontinuation of Treatment with Paxil** sections. It also adds two new subsections entitled **PRECAUTIONS-PREGNANCY-Nonteratogenic Effects** and **DOSAGE AND ADMINISTRATION-Special Populations-Treatment of Pregnant Women During the Third Trimester**.

We have completed the review of your resubmission to NDA 20-031/S-039/S-040, 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 March 5, 2004 labeling. Accordingly, these applications are approved effective on the date of this letter.

Additionally, since our approval letter dated January 27, 2004, supercedes the labeling revisions proposed in supplemental applications 20-936/S-015/S-016, we are going to administratively close these supplements and retain them in our files.

We note, however, that the term "Pregnant" was inadvertently omitted in the new subsection entitled **Treatment of Pregnant Women During the Third Trimester** in the **DOSAGE AND ADMINISTRATION-Special Populations** section of the Paxil Immediate-Release labeling. We request that you correct this in the next printing of labeling for clarity and consistency with Paxil CR labeling.

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}

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/

Russell Katz

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