DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-031/S-048/051/052
NDA 20-936/S-022/026/027
NDA 20-710/S-015/016

GlaxoSmithKline
Attention: James Murray
Director Regulatory Affairs
One Franklin Plaza
PO Box 7929
Philadelphia, PA 19101-7929

Dear Mr. Murray:

We acknowledge receipt of your supplemental new drug applications dated June 16, 2005 (NDAs 20-031/S-048, 20-936/S-022), October 7, 2005 (NDA 20-936/S-026), October 21, 2005 (NDAs 20-031/S-051 and 20-710/S-015) and December 5, 2005 (NDAs 20-031/S-052, 20-936/S-027, and 20-710/S-016) submitted under section 505(b) of the Federal Food Drug and Cosmetic Act for Paxil (paroxetine hydrochloride) tablets (NDA 20-031), Paxil (paroxetine hydrochloride) CR tablets (NDA 20-936), and Paxil (paroxetine hydrochloride) suspension (NDA 20-710).

These supplemental applications provide for the following revisions to product labeling:

20-031/S-048
20-936/S-022

- Under CONTRAINDICATIONS - to include a statement that concomitant use of paroxetine in patients taking pimozide is contraindicated.

- Under PRECAUTIONS – the addition of a new subsection entitled "Pimozide" under the PRECAUTIONS-Drug Interactions section.

20-031/S-051
20-936/S-026
20-710/S-015

The supplement informs the Agency of GSK's submitted change to the packaging (carton & container) by including a black box warning and a Medication Guide in all of the paroxetine products' labeling to describe the potential for increased risk of suicidal ideation in children and adolescents who take antidepressants, and to distribute each product presentation in unit-of-use packaging to ensue every patient receives the MedGuide.

20-031/S-052
20-936/S-027
20-710/S-016

This supplement provides for revisions to the WARNINGS and PRECAUTIONS-Pregnancy section to include information on the study of major congenital malformation among infants born to women dispensed paroxetine in the first trimester. The Pregnancy category also changed from a "C" to a "D" category.

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 December 5, 2005. Accordingly, these supplemental applications are approved effective on the date of this letter.

[(b4)]

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 Renmeet Gujral, Pharm. D., Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry 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
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