DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-936/S-039

APPROVAL LETTER

GlaxoSmithKline
Attention: Leo Lucisano, R.Ph.
Regional Director, CMC Regulatory Affairs
Five Moore Drive
P. O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Lucisano:

Please refer to your supplemental new drug application dated March 19, 2009, received March 19, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil CR (paroxetine hydrochloride) Controlled Release Tablets 12.5 mg, 25 mg, and 37.5 mg.

We acknowledge receipt of your submissions dated June 23, 2009 and June 29, 2009.

This supplemental new drug application provides for the transfer of the manufacture of Paxil CR Tablets (NDA 20-936 approved February 16, 1999) from GlaxoSmithKline's Cidra, Puerto Rico facility to GlaxoSmithKline's Mississauga, Canada facility.

We completed our review of this supplemental new drug application. This supplement is approved.

As part of our review, we evaluated your use of multivariate (MVA) models for predicting stability of PAXIL CR drug product. We find that the design space and dissolution MVA models reasonably predict stability, as confirmed by your actual data. Please note that the suitability of this approach for other products would be evaluated on a case-by-case basis.

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, contact LCDR Kofi Ansah, Senior Regulatory Project Manager, at (301)796-4158.

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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