



NDA 20-031/S-061
NDA 20-936/S-038
NDA 20-710/S-025

GlaxoSmithKline
Attention: Randal L. Batenhorst, Pharm.D.
Vice President, US Regulatory Affairs- Neurosciences
5 Moore Drive
Research Triangle Park, NC 27709-3398

Dear Dr. Batenhorst:

Please refer to your supplemental new drug application dated December 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil (paroxetine HCl) tablets (NDA 20-031), Paxil (paroxetine HCl) CR tablets (NDA 20-936), and Paxil (paroxetine) oral suspension (NDA 20-710).

Reference is also made to an FDA letter dated December 4, 2008 notifying you, under section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Paxil and Paxil CR. This information pertains to the risk of neuroleptic malignant syndrome associated with use of selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs), including Paxil and Paxil CR.

We additionally refer to an e-mail from LCDR Renmeet Grewal, of the FDA, to you dated January 23, 2009, requesting additional revisions to the labeling, and to your e-mail dated January 26, 2009, accepting this language.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission **“SPL for approved supplements NDAs 20-031/S-061, 20-936/S-038, & 20-710/S-025.”**

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Renmeet Grewal, Pharm. D., Senior 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

Enclosure

**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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