



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-644/S-031
NDA 20-358/S-035
NDA 21-515/S-012

GlaxoSmithKline
Attention: Mary E. Martinson
Director, Psychiatry US Regulatory Affairs
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Martinson:

We acknowledge receipt of your supplemental new drug applications dated August 30, 2005, for Wellbutrin Immediate Release Tablets (NDA 18-644), Wellbutrin SR (bupropion hydrochloride) Sustained-Release Tablets (NDA 20-358), and Wellbutrin XL (bupropion hydrochloride) Extended-Release Tablets (NDA 21-515).

We additionally acknowledge receipt of your amendment dated December 2, 2005.

Reference is also made to an Agency approval letter for applications 18-644/S-030, 20-358/S-034, and 21-515/S-009 dated January 12, 2005, which provided for labeling revisions to include a black box and Medication Guide pertaining to pediatric suicidality.

These "Changes Being Effected" supplemental new drug applications provide for additions to the **Warnings to Physicians-Clinical Worsening and Suicide Risk** section based upon APA guidelines.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 2, 2005.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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 Dr. Renmeet Gujral, 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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