DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18644/S-046, S-047
NDA 20358/S-053, S-054

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Jaisri Giridhar, PhD, DABT, RAC
Manager, Neurosciences
Global Regulatory Affairs
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709-3398

Dear Dr. Giridhar:

Please refer to the following Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NDA 18644 Wellbutrin (bupropion hydrochloride) 75 mg and 100 mg Tablets and NDA 20358 Wellbutrin SR (bupropion hydrochloride) Sustained-Release 100 mg, 150 mg, and 200 mg Tablets:

- Prior Approval Labeling Supplements NDA 18644/S-046 and 20358/S-053, dated and received November 30, 2012, provide for labeling revisions to the **Pregnancy** section of labeling. The June 21, 2013 submission constituted a complete response to our May 28, 2013 complete response letter. We acknowledge receipt of your amendments dated December 20, 2013.

- Prior Approval Labeling Supplements NDA 18644/S-047 and 20358/S-054, dated December 11, 2012 and received December 12, 2012, proposing a draft label to be in compliance with the Physician Labeling Rule.

  We acknowledge receipt of your amendments dated:

March 13, 2013	April 19, 2013	December 4, 2013
April 1, 2013	June 21, 2013	December 20, 2013
April 4, 2013	September 13, 2013	
April 9, 2013	October 24, 2013	

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

We note that your December 20, 2013, submissions include final printed labeling (FPL) for your package inserts and Medication Guides. We have not reviewed the FPL. You are responsible

for assuring that the wording in the printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling (Full Prescribing Information and Medication Guide)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
12/23/2013