DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018644/S-044, NDA 20358/S-051

SUPPLEMENTAL APPROVAL
RELEASE REMS REQUIREMENT

GlaxoSmithKline
Attention: Mary E. Martinson
Senior Director, Psychiatry, US Regulatory Affairs
P.O. Box 13398, Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Ms. Martinson:

Please refer to your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Wellbutrin (bupropion hydrochloride) 75 mg and 100 mg Tablets (S-044) and Wellbutrin SR (bupropion hydrochloride) Sustained-Release 100 mg, 150 mg, and 200 mg Tablets (S-051), dated and received August 24, 2011.

We also acknowledge receipt of your amendments dated September 8, 2011, October 12, 2011, and June 27, 2012.

These supplemental new drug applications provide for your risk evaluation and mitigation strategy (REMS) assessment as well as propose to eliminate the requirement for the approved Wellbutrin and Wellbutrin SR REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

This supplemental new drug application proposes to eliminate the requirement for the approved Wellbutrin and Wellbutrin SR risk evaluation and mitigation strategy (REMS). The REMS for Wellbutrin and Wellbutrin SR (bupropion hydrochloride) was originally approved on February 26, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an

element of the approved REMS to ensure that the benefits of Wellbutrin and Wellbutrin SR (bupropion hydrochloride) outweigh its risks.

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}

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 P LAUGHREN
08/02/2012