DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-711/S-028

GlaxoSmithKline
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

Attention: Mary E. Martinson
Director, Psychiatry US Regulatory Affairs

Dear Ms. Martinson:

Please refer to your supplemental new drug application dated and received September 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyban® (bupropion hydrochloride) Sustained-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for revised labeling that combines the Patient Information leaflet and Medication Guide for ZYBAN SR into the same format as the Medication Guide for WELLBUTRIN XL (NDA 21-515) and provides for other changes in ZYBAN SR labeling that make the labeling consistent with WELLBUTRIN XL labeling, as provided for in the June 12, 2006, approval by the Division of Psychiatry Products (DPP) for NDA 21-515, supplement 010.

We note that these proposed labeling changes have been incorporated into the labeling for WELLBUTRIN® (bupropion hydrochloride) Tablets (NDA 18-644/S-035) and WELLBUTRIN SR® (bupropion hydrochloride) Sustained-Release Tablets (NDA 20-358/S-042), as provided for in the January 29, 2007, approval letter from DPP, and also have been incorporated in the labeling for GlaxoSmithKline's unbranded Bupropion Hydrochloride Sustained-Released Tablets (products for depression and for smoking cessation), which are distributed by Watson Laboratories, Inc.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) you have included in this submission, and attached to this letter (enclosure).

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

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 Dominic Chiapperino, Regulatory Project Manager, at (301) 796-1183.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

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