DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-711/S-013, S-014, S-016, S-018

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

Attention: James E. Murray
Vice President, Regulatory Affairs

Dear Mr. Murray:

Please refer to your supplemental new drug applications dated May 26, 2000 (S-013), February 8, 2001 (S-014), August 7, 2001 (S-016) and April 22, 2002 (S-018), received May 30 (S-013), February 9, 2001 (S-014), August 8, 2001 (S-016) and April 23, 2002 (S-018), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyban (buproprion hydrochloride) Sustained-Release Tablets.

We acknowledge receipt of your submissions dated October 3 and November 7, 2000, March 1, 2001, (S-013), and February 11, 2002 (S-013 and S-014),

S-013 provides for revised **CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections of the package insert, and a revised **INFORMATION FOR THE PATIENT** Leaflet.

S-014 provides for revised **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert.

S-016 provides for revised **WARNINGS, PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections of the package insert, and a revised **INFORMATION FOR THE PATIENT** Leaflet.

S-018 provides for revised **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert.

We have completed our review of these supplemental applications, as amended, and they are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and information for the patient leaflet).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-711/S-013, S-014, S-016, S-018)." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Victoria Kao, Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
and Addiction Drug 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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