DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-358/SCM-028

GlaxoSmithKline
Attention: Leo J. Lucisano, R.Ph.
Regional Director, CMC Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Lucisano:

Please refer to your supplemental new drug application dated March 27, 2002, received March 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for WELLBUTRIN SR (bupropion hydrochloride) Sustained-Release Tablets 100 mg and 150 mg.

This CBE-30 supplemental new drug application provides for the GlaxoSmithKline facility in Mississauga, Canada as an alternate primary and secondary packaging site for WELLBUTRIN SR (bupropion hydrochloride) Sustained-Release Tablets.

We have completed the review of this supplemental application, and it is approved.

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 Doris Bates, Ph.D., Regulatory Project Manager, at (301) 594-5536.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, Ph.D.
Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Thomas Oliver

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