DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18644/SCM-025

GlaxoSmithKline
Attention: Leo J. Lucisano, R.Ph.
Director, CMC Post-Approval Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Lucisano:

Please refer to your supplemental new drug application dated October 15, 2001, received October 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for WELLBUTRIN (bupropion hydrochloride) Tablets.

This supplemental new drug application seeks to qualify (b)(4)---------- as an alternate manufacturing site for the bupropion hydrochlo----------TRIN SR Tablets.

Additionally, this supplement seeks to :

A) Register an increased manufacturing batch size,
B) Register an isolation by filteration step in Stages 1 and 2 of the synthesis,
C) Register a heel recovery step during the drug synthesis,
D) Register methyl ethyl ketone as alternate denaturant of ethanol,
E) Register alternate specifications and test methods for starting materials, reagents, solvents, and auxillary materials.

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 Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Acting 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/

Hasmukh Patel
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