DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 12342 / S-063 **SUPPLEMENT APPROVAL**

GlaxoSmithKline
Attention: Eric B. Benson
Senior Director
US Regulatory Affairs
5 Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Benson:

Please refer to your supplemental new drug application dated and received December 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Parnate (tranylcypromine sulfate) tablets 10 mg.

This "Prior Approval" supplemental new drug application provides for the following labeling changes:

1. Addition of "which may be found in many herbal preparations as well as," to Contraindications section, subsection 7**.**
2. Addition of "Cerebral hemorrhage may also occur." to Contraindications section, subsection 7.
3. Update the language in the Contraindications section, subsection 10 *"In combination with cheese and other foods containing tyramine."*

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/CM072392.pdf.

LETTERS TO HEALTH CARE PROFESSIONALS
If you issue a letter communicating important safety related information about this drug product

(i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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, contact Renmeet Grewal, Pharm.D. RAC, Senior Regulatory Project Manager, at renmeet.grewal@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

Enclosure:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-12342	SUPPL-63	GLAXOSMITHKLINE	PARNATE TABLETS

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
05/14/2010