DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 12-342/S-056/S-057

GlaxoSmithKline
Attention: Maria Wagner, Ph.D.
Senior Director, U.S. Regulatory Affairs, Psychiatry
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Wagner:

Please refer to your supplemental new drug applications dated August 30, 2005, and November 4, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Parnate (tranylcypromine sulfate) 10 mg Tablets.

These supplements provide for the following revisions:

S-056
The supplement provides for additions to the **Warnings to Physicians-Clinical Worsening and Suicide Risk** section based upon APA guidelines.

S-057
This supplement informs the Agency that GSK is making Medication Guides available for distribution to patients by providing a Medication Guide with each trade package.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and container labeling submitted on August 30, 2005, and November 4, 2005), which incorporates the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental application are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplements, have been made.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Dr. Renmeet Gujral, Regulatory Project Manager, at (301) 796-1080.

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
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