DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 11-909/S-035

Pfizer Pharmaceuticals
Attention: Roy von Kutzleben, DVM, Ph.D., FTOPRA
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-3184

Dear Dr. Kutzleben:

Please refer to your supplemental new drug application dated November 5, 2004, and received November 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nardil (phenelzine sulfate) 15 mg Tablets.

We additionally refer to an Agency approvable letter dated January 12, 2005 as well as a letter dated January 26, 2005 clarifying our requested revisions to the labeling for the above supplemental applications.

We acknowledge receipt of your submissions dated February 2, 2005, providing for a complete response to our January 12, and 26, 2005 Agency letters.

These supplements provide for the addition of a boxed warning and other changes to product labeling and the addition of a Medication Guide pertaining to pediatric suicidality.

We have completed the review of this supplemental application, and we believe that the final approved labeling must incorporate the changes as noted below. We consider this revision as minor within the meaning of 21 CFR 314.105(b). Accordingly, this application is approved with the February 2, 2005 labeling changes, as modified below, effective on the date of this letter.

We note that you have retained the subsection in the **WARNINGS** section entitled **Use in Pediatric Patients**. This subsection should be deleted since it is now superseded by the new **Pediatric Use** section in the **PRECAUTIONS** section, and the **Pediatric Use** section should be updated with the following language:

[This section should be located under **PRECAUTIONS, Pediatric Use**.]

Pediatric Use-Safety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS—Clinical Worsening and Suicide Risk). Anyone considering the use of Nardil (phenelzine sulfate) in a child or adolescent must balance the potential risks with the clinical need. Nardil, as with other hydrazine derivatives, has been reported to induce pulmonary and vascular tumors in an uncontrolled lifetime study in mice.

You should submit final printed labeling (FPL) identical to the enclosed labeling (text for the package insert and Medication Guide). For administrative purposes, this submission should be designated "FPL for approved supplement 11-909/S-035." Also, you should provide a date when the labeling will be available on your products. Since we have developed standardized labeling for all antidepressants used in children because of safety concerns associated with the use of these products in children, final printed labeling should be available on your WEB page within two weeks of the date of this letter, and on all products within 30 days. Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

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., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Russell Katz
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