DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 11-909/S-033

Pfizer Inc.
Attention: Alan Dunbar
Regulatory Affairs
235 E 42nd Street
New York, NY 10017

Dear Mr. Dunbar:

We acknowledge receipt of your supplemental new drug application dated March 27, 2003, and amended on July 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nardil (phenelzine sulfate) 15 mg Tablets.

Reference is also made to an electronic communication dated August 26, 2003, from you to Mr. Paul David, of this Agency, agreeing to some minor labeling revisions to your proposed labeling.

This "Prior Approval" supplemental new drug application provides for the addition of a **Pharmacokinetics** subsection into the **CLINICAL PHARMACOLOGY** section, and the removal of "corn starch" from the **DESCRIPTIONS** section of labeling.

We have completed the review of this supplemental application, S-033, 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 attached, agreed upon, labeling. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the attached labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 11-909/S-033." Approval of this submission by FDA is not required before the labeling is used.

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 Mr. 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

Attachment

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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