DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-909/S-036

Pfizer Inc.
Attention: Carol J. Haley, Ph.D.
Worldwide Regulatory Strategy
235 East 42nd Street
New York, New York 10017

Dear Dr. Haley:

We acknowledge receipt of your supplemental new drug application dated August 18, 2006, received August 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nardil (phenelzine sulfate) 15mg tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for removal of the [redacted], decrease tablet count, reduced bottle size, and revisions to the **CONTRAINDICATIONS**, **PRECAUTIONS**, and **HOW SUPPLIED** sections of product labeling.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling (FPL) submitted on August 18, 2006.

We note that you have made the following labeling revisions (underline font denotes additions and strike through font denotes deletions):

CONTRAINDICATIONS
NARDIL should not be used in patients who are hypersensitive to the drug or its ingredients, with pheochromocytoma, congestive heart failure, severe renal impairment or renal disease, a history of liver disease, or abnormal liver function tests.

Concomitant use with meperidine is contraindicated (see WARNINGS).

At least 14 days should elapse between the discontinuation of an MAO inhibitor and the start of a serotonin re-uptake inhibitor or vice-versa, with the exception of fluoxetine.

PRECAUTIONS
NARDIL should be used with caution in diabetes mellitus; increased insulin sensitivity may occur. Requirements for insulin or oral hypoglycemics may be decreased.

Administration of guanethidine to patients receiving an MAO inhibitor can produce moderate to severe hypertension due to release of catecholamines. At least two weeks should elapse between withdrawal of the MAO inhibitor and the initiation of guanethidine. (see CONTRAINDICATIONS)

HOW SUPPLIED
Each NARDIL tablet is orange, biconvex, film-coated, and engraved with “P-D 270” and contains phenelzine sulfate equivalent to 15 mg of phenelzine base.
~~NDC 0071-0350-24~~NDC 0071-0350-60. Bottle of ~~100~~60

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call LCDR Renmeet Grewal, Pharm.D., 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

Enclosure

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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