DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-442/S-029

Pfizer Inc.
Attention: Ms. Marianne Kopelman
235 East 42nd Street
New York, NY 10017

Dear Ms. Kopelman:

Please refer to your supplemental new drug application dated March 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Minipress (prazosin hydrochloride) 1, 2, and 5 mg Capsules.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised as follows:

1. The CONTRAINDICATIONS section has been changed from:

   None known.

   To:

   MINIPRESS is contraindicated in patients with known sensitivity to quinazolines, prazosin or any of the inert ingredients.

2. The following has been added to the WARNINGS section:

   As with all alpha-blockers, MINIPRESS (prazosin hydrochloride) may cause syncope with sudden loss of consciousness.

3. The following statement and new subsections have been added to the ADVERSE REACTIONS section:

   In post-marketing experience, the following adverse events have been reported:
   Autonomic Nervous System: flushing.
   Body As A whole: allergic reaction, asthenia, malaise, pain.
   Cardiovascular, General: angina pectoris, hypertension.
   Endocrine: gynecomastia.
   Heart Rate/Rhythm: bradycardia.
   Psychiatric: insomnia.
   Skin/Appendages: urticaria.
   Vascular (Extracardiac): vasculitis.
   Vision: eye pain.

4. The HOW SUPPLIED section has been revised from:

Strength	Capsule Color	Capsule Code	NDC	Package Size
MINIPRESS 1 mg	White	431	0663-4310-71 0069-4310-71 0663-4310-82 0663-4310-41	250's 250's 1000's 100 (10x10) Unit Dose
MINIPRESS 2 mg	Pink and White	437	0663-4370-71 0663-4370-82 0663-4370-41	250's 1000's 100 (10x10) Unit Dose
MINIPRESS 5 mg	Blue and White	438	0663-4380-71 0663-4380-73 0663-4380-41	250's 500's 100 (10x10) Unit Dose

To:

Strength	Capsule Color	Capsule Code	NDC	Package Size
MINIPRESS 1 mg	White	431	0069-4310-71	250's
MINIPRESS 2 mg	Pink and White	437	0069-4371-71	250's
MINIPRESS 5 mg	Blue and White	438	0069-4380-71	250's

We have completed the review of this supplemental application, as amended, 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 final printed labeling included in your March 28, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, please call:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal 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/

Raymond Lipicky

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