DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-442/S-033

Pfizer, Inc.
Attention: Kathleen Collins
Manager, WW Regulatory Strategy
235 East 42nd St.
New York, NY 10017

SUPPLEMENT APPROVAL

Dear Ms. Collins:

Please refer to your supplemental new drug application (NDA) dated March 19, 2009 and received March 19, 2009,submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Minipress (prazosin hydrochloride) 1, 2, and 5 mg Capsules.

We also refer to our letter dated February 19, 2009, notifying you, under Section 505(o)(4) of the FDCA, of new safety information concerning Intraoperative Floppy Iris Syndrome that we believe should be included in the labeling for Minipress (prazosin hydrochloride). We also refer to our previous supplement request letter dated July 21, 2005, and your response dated December 8, 2008.

Your supplemental new drug application provides for the following revisions to the labeling for Minipress (prazosin hydrochloride) consistent with our February 19, 2009, letter:

1. To add the following subheading to the beginning of the **PRECAUTIONS** section:

   General
   Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients treated with alpha-1 blockers. This variant of small pupil syndrome is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions. The patient's ophthalmologist should be prepared for possible modifications to the surgical technique, such as the utilization of iris hooks, iris dilator rings, or viscoelastic substances. There does not appear to be a benefit of stopping alpha-1 blocker therapy prior to cataract surgery.

2. In the **ADVERSE REACTIONS** section, to add the following subheading to the end of the list following the paragraph that states, "In post-marketing experience, the following adverse events have been reported:"

Special Senses: During cataract surgery, a variant of small pupil syndrome known as Intraoperative Floppy Iris Syndrome (IFIS) has been reported in association with alpha-1 blocker therapy (see **PRECAUTIONS**).

3. Other minor modifications to the labeling (i.e., formatting changes, new revision date).

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 17-442/S-033**."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, please call Dan Brum, PharmD, MBA, RAC, Regulatory Project Manager, at (301) 796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Appendix A: Agreed-upon labeling text

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

/s/

Norman Stockbridge

4/6/2009 11:33:23 AM