DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-668/S-021

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 July 2, 2009 and received July 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardura (doxazosin mesylate) 1, 2, 4, and 8 mg Tablets.

We also refer to our supplement request letter dated June 2, 2009.

Your supplemental new drug application provides for the following revisions to the labeling for Cardura (doxazosin mesylate):

1. Add the following text to the **PRECAUTIONS/Drug Interactions** section of the package insert:

   - Concomitant administration of CARDURA with a phosphodiesterase-5 (PDE-5) inhibitor can result in additive blood pressure lowering effects and symptomatic hypotension (see DOSAGE AND ADMINISTRATION).

2. Add the following text to the **DOSAGE AND ADMINISTRATION** section of the package insert:

   - Concomitant administration of CARDURA with a PDE-5 inhibitor can result in additive blood pressure lowering effects and symptomatic hypotension; therefore PDE-5 inhibitor therapy should be initiated at the lowest dose in patients taking CARDURA.

3. Delete the following text from the **HOW SUPPLIED** section:

   CARDURA TABLETS (doxazosin mesylate) are available as 1 mg (white), 2 mg (yellow), 4 mg (orange) and 8 mg (green) scored tablets.

   Add the word “scored” to the first paragraph (second sentence) of the **HOW SUPPLIED** section (underscore shows addition):

CARDURA (doxazosin mesylate) is available as colored tablets for oral administration. Each scored tablet contains doxazosin mesylate equivalent to 1 mg (white), 2 mg (yellow), 4 mg (orange) or 8 mg (green) of the active constituent, doxazosin.

4. We note minor editorial changes throughout the labeling.

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 19-668/S-021**."

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}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: 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/

Mary Southworth

7/10/2009 11:48:05 AM