DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-668/S-022 **SUPPLEMENT APPROVAL**

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

Dear Ms. Collins:

Please refer to your supplemental new drug application (NDA) dated October 29, 2009 and received October 30, 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 acknowledge receipt of your submission dated January 11, 2010.

This "Changes Being Effected" supplemental new drug application was submitted to align the patient information leaflet (PIL) with certain safety information included in the package insert (USPI). This supplement provides for the following two additions to the PIL under the section "**How to Take CARDURA and What You Should Know While Taking CARDURA for BPH**":

- Tell your surgeon if you take or have taken CARDURA if you plan to have surgery for cataracts (clouding of the eye). During cataract surgery, a condition called Intraoperative Floppy Iris Syndrome (IFIS) can happen if you take or have taken CARDURA.

- If you use CARDURA with an oral erectile dysfunction medicine (phosphodiesterase-5 (PDE-5) inhibitor), it can cause a sudden drop in your blood pressure and you can become dizzy or faint. Talk with your healthcare provider before using PDE-5 inhibitors.

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

CONTENT OF LABELING

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)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "**SPL for approved NDA 19-668/S-022**".

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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, Pharm.D., 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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19668	SUPPL-22	PFIZER LABORATORIES DIV PFIZER INC	CARDURA

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

/s/

MARY R SOUTHWORTH
01/14/2010