



NDA 19-668/S-012

Pfizer, Inc.
Attention: Mr. Alan J. Dunbar
235 East 42nd Street
New York, NY 10017

Dear Mr. Dunbar:

Please refer to your supplemental new drug application dated August 27, 1999, 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 acknowledge receipt of your submission dated February 12, 2003.

Your submission of February 12, 2003 constituted a complete response to our January 18, 2002 action letter.

This supplemental new drug application provides final printed labeling revised as follows:

1. In the PRECAUTIONS section, the "Use in Elderly" subsection has been changed to "Geriatric Use" and the following has been added at the end of the section:

Clinical studies of CARDURA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

2. In the OVERDOSAGE section, "paracetamol" has been replaced with "acetaminophen" in the second sentence.
3. In the Patient Package Insert, under "Treatment Options," third bullet, after Proscar®, "(finasteride) [by Merck & Co.]" has been added.

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 final printed labeling (FPL) submitted on February 12, 2003.

At the time of the next printing, please make the following changes:

1. Change the storage statement in the HOW SUPPLIED section from:

Recommended Storage: Store below 86°F (30°C).

To:

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)
[see USP Controlled Room Temperature]

2. In the Patient Package Insert, under "Treatment Options," please change the first sentence of the third bullet from:

Treatment with the medication class of 5-alpha reductase inhibitors (e.g., Proscar® (finasteride) [by Merck & Co.]).

To:

Treatment with the medication class of 5-alpha reductase inhibitors (e.g., Proscar® (finasteride)).

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, 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. Melissa Robb
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, 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
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/s/

Doug Throckmorton
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