DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 19-668/S-015

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

Dear Mr. Dunbar:

Please refer to your supplemental new drug application dated October 17, 2001, 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 your submission of December 7, 2001.

This "Changes Being Effected" supplemental new drug application provides final printed labeling revised to add, “Skin Disorders: uticaria” to the post-marketing experience section of the ADVERSE REACTIONS section.

We have completed the review of this supplemental application 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 October 17, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We also refer to the January 17, 2002 telephone conversation between you and Ms. Zelda McDonald wherein she requested that the patient package insert for Benign Prostatic Hyperpalsia be added to the end of the package insert in accordance with 21 CFR 201.57 (f)(2). Please make this change at the time of your next printing.

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
1/23/02 11:50:02 AM