CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-269

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-269

Pfizer Inc.
Attention: Alan Dunbar
Director, Worldwide Regulatory Strategy
235 E 42nd Street
New York, NY 10017

Dear Mr. Dunbar:

Please refer to your new drug application (NDA) dated April 20, 2001, received April 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardura XL® (doxazosin mesylate) Extended Release Tablets.

We acknowledge receipt of your submissions dated April 20, June 15 and 28, August 3, September 6, 2001, February 11 and 28, May 10, 2002, December 17, 2003, April 2, May 14 and 18, June 17, August 20, November 22, 24 and 25, December 2, 2004, and February 18 and 22, 2005.

The August 20, 2004, submission constituted a complete response to our June 16, 2004 action letter.

This new drug application provides for the use of Cardura XL® (doxazosin mesylate) Extended Release Tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted February 18, 2005). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-269.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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, call Martin Kaufman, D.P.M., M.B.A., Regulatory Project Manager, at (301) 827-4234.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products (HFD-580)
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Daniel A. Shames
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