DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-540

Pfizer Inc.
Attention: Mr. Robert Clark
235 East 42nd Street
New York, NY 10017

Dear Mr. Clark:

Please refer to your new drug application (NDA) dated March 31, 2003, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Caduet (amlodipine besylate/atorvastatin calcium) 5/10, 10/10, 5/20, 10/20, 5/40, 10/40, 5/80 and 10/80 mg Tablets.

We acknowledge receipt of your submissions dated June 30, July 8, 31, August 7, 8 (two), 11, 18, September 24, 26 (two), October 9, 10, 20, 31 (two), November 5, 11 (two), 12 (two), 19, December 12 (two), 19 (two), 2003, January 16, 20 (two), 21, 26, 28 (two), and 30, 2004.

This new drug application provides for the use of Caduet (amlodipine besylate/atorvastatin calcium) in patients for whom treatment with both amlodipine and atorvastatin is appropriate as indicated in the agreed-upon labeling.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert. 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 21-540**." Approval of this submission by FDA is not required before the labeling is used.

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/ the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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The proposed dissolution method and specifications are as follows: USP Type II apparatus at a paddle speed of 75 rpm in 900 mL of phosphate buffer pH 6.8 with a Q of (b) in 15 minutes for both amlodipine and atorvastatin.

An expiration date of 18 months is granted for CADUET tablets 5/10, 5/20, 5/40, 5/80, 10/10, 10/20, 10/40 and 10/80 mg, packaged in foil/foil blisters and HDPE bottles of 30 tablets. Any extension of the expiration date beyond 18 months should be based on real-time stability data generated according to the amended post-approval stability protocol dated January 28, 2004.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 note that you have fulfilled the pediatric study requirement for this application.

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 Ms. Denise M. Hinton, Regulatory Health Project Manager, at (301) 594-5333.

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

Enclosure: Draft label

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

/s/

Norman Stockbridge
1/30/04 02:44:18 PM
For Douglas Throckmorton