DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-540/S-006

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

Dear Mr. Clark:

Please refer to your supplemental new drug application dated July 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Caduet (amlodipine besylate and atorvastatin calcium) 2.5/10, 2.5/20, 2.5/40, 5/10, 5/20, 10/20, 5/40, 10/40, 5/80 and 10/80 mg Tablets.

We acknowledge receipt of your submission dated May 26, 2006. This submission constituted a complete response to our December 30, 2005 action letter.

This supplemental new drug application provides language for a Patient Package Insert (PPI) for Caduet.

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

The final printed labeling (FPL) must be identical to the enclosed labeling text for the patient package insert submitted May 26, 2006. These revisions are terms of the approval of this application.

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 supplement NDA 21-540/S-006**." Approval of this submission by FDA is not required before the labeling is used.

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 Project Manager, at (301) 796-1090.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (PPI)

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

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