DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-540/S-011

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

Dear Mr. Clark:

Please refer to your electronic supplemental new drug application dated October 12, 2005 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, 10/10, 5/20, 10/20, 5/40, 10/40, 5/80 and 10/80 mg Tablets.

We acknowledge receipt of your submission dated March 16, 2007.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to the **Clinical Studies/** ***Clinical Studies with Atorvastatin,*** **INDICATIONS AND USAGE, and ADVERSE REACTIONS/*Clinical Adverse Experiences*** sections of the package insert to include new indications, based on the results of the Treating to New Targets Study (TNT), for the use of atorvastatin in adult patients with clinically evident coronary heart disease to reduce the risk of non-fatal myocardial infarction, fatal and non-fatal stroke, angina, revascularization procedures, and hospitalization for congestive heart failure.

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 agreed-upon labeling text. The final printed labeling (FPL) must be identical to the submitted package insert submitted on March 16, 2007.

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-011**". 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, Commander 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 (Package Insert)

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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