



**DEPARTMENT OF HEALTH & HUMAN
SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-540/S-009

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 December 29, 2006.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the Caduet package insert to include new labeling language in the last approved labeling for Lipitor (atorvastatin calcium). The new labeling language is regarding use in patients with recent stroke or TIA as seen in a post-hoc analysis of hemorrhagic stroke in the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) trial and the post marketing adverse event of tendon rupture.

We have completed our review of this application and 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 submitted package insert submitted on December 29, 2006.

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-009**". 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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