



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-540/S-003

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

Dear Mr. Clark:

Please refer to your supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Caduet (amlodipine besylate/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 August 2, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for new language in the atorvastatin sections of the label consistent with the July 29, 2004 approved labeling for Lipitor and for revisions to include reference to 2.5 mg tablet combinations.

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 draft labeling submitted on August 2, 2004. The final printed labeling (FPL) must be identical to the enclosed package insert.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-540/S-003." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
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, please call:

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

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug 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
9/27/04 06:51:50 AM