



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-540/S-018

APPROVAL LETTER

Pfizer Global Pharmaceuticals
Attention: Liza Karpiak, RPh, M.S.
Associate Director, US Regulatory Affairs
235 East 42nd Street
MS 685/18/03
New York, NY 10017

Dear Ms. Karpiak:

Please refer to your supplemental new drug application dated May 13, 2009, received May 13, 2009, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Caduet (amlodipine besylate/atorvastatin calcium) 2.5/10 mg, 2.5/20 mg, 2.5/40 mg, 5/10 mg, 5/20 mg, 5/40 mg, 5/80 mg, 10/10 mg, 10/20 mg, 10/40 mg and 10/80 mg Tablets.

We also refer to your supplement request letter dated January 13, 2009.

This "Changes Being Effected" supplemental new drug application provides for changes to the **ADVERSE REACTIONS** section of the label.

The following changes have been made:

1. In **ADVERSE REACTIONS/The Atorvastatin Component of CADUET/Postintroduction Reports with Atorvastatin**, "hepatic failure" has been added to the list of adverse events.
2. The revision date has been updated.
3. Minor editorial revisions.

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 electronic final printed labeling (FPL) submitted on May 13, 2009.

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
Food and Drug Administration
Suite 12B05
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:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager
(301) 796 3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure : Approved Labeling

**This is a representation of an electronic record that was signed electronically and
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/s/

Mary Southworth
7/20/2009 03:57:12 PM