



NDA 21540/S-042
NDA 21540/S-043

SUPPLEMENT APPROVAL

PF Prism CV
C/o: Pfizer Inc.
Attention: Marcio De Godoy, MBA, PharmD, PhD
Senior Manager, Pfizer Essential Health Global Regulatory Affairs R&D
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. De Godoy:

Please refer to your Supplemental New Drug Applications (sNDA) dated 15 February 2018 (S042), and 27 July 2018 (S043) and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Caduet® (amlodipine besylate/ atorvastatin calcium) tablets 2.5/10mg, 5/10; 10/10; 5/20; 10/20; 5/40; 10/40; 5/80; 10/80 mg.

We also refer to our approval letter dated September 12, 2018 which contained the following error: the 2.5/10 mg strength was not listed in the letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain September 12, 2018, the date of the original approval letter.

This Prior Approval supplemental new drug application for S-042 proposes to harmonize with the currently approved label for Lipitor the presentation of drug interaction data for atorvastatin in section 7.10, and 12.3, as well as update information regarding the effect of co-administered colestipol on the pharmacokinetics of atorvastatin in section 12.3.

This "Changes Being Effected" supplemental new drug application for S-043 proposes to harmonize with revisions approved for Lipitor on June 23, 2017.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, text for the patient package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Alexis Childers, Sr. Regulatory Project Manager, at (301) 796-0442.

Sincerely,

{See appended electronic signature page}

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

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ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
09/12/2018