



NDA 012151/S-067

SUPPLEMENT APPROVAL

Pfizer, Inc. c/o GDSearle, LLC
Attention: Michele Burtness
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms Burtness:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 25, 2011, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aldactone (spironolactone) 25 mg, 50 mg, and 100 mg Tablets.

This “Changes Being Effected” supplemental new drug application provides for labeling revised as follows:

1. Under **CLINICAL STUDIES**, the description under Figure 2 was changed from:

Figure 2: The size of each box is proportional to the sample size as well as the event rate. ACEI denotes angiotensin-converting enzyme inhibitor, LVEF denotes left ventricular ejection fraction, Cr Clearance denotes creatinine clearance, and Ser Creatinine denotes serum creatinine

To:

Figure 2: The size of each box is proportional to the sample size as well as the event rate. LVEF denotes left ventricular ejection fraction, Ser Creatinine denotes serum creatinine, Cr Clearance denotes creatinine clearance, and ACEI denotes angiotensin-converting enzyme inhibitor.

2. Under **ADVERSE REACTIONS**, the following text was added:

Skin: Stevens-Johnson Syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS).

3. Under **HOW SUPPLIED**, the following was deleted:

<u>NDC Number</u>	<u>Size</u>
0025 1001 51	Bottle of 500
0025 1041 34	Carton of 100 unit dose
0025 1031 34	Carton of 100 unit dose

4. There are several editorial changes noted throughout the label, i.e. Aldactone was changed to ALDACTONE, the word “which” was changed to “that”, “Rx only” was deleted, and the cross references were re-formatted)
5. The revision date, version number, and company logo were updated.

There are no other changes from the last approved package insert.

We have completed our review of this supplemental application, and it is 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 package insert), with the addition of any labeling changes in pending “Changes Being Effected” (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 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:

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

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 1
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
09/22/2011