DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-151/S-062

Pfizer Global Pharmaceuticals
Attention: Kathy Collins
235 East 42nd Street
New York, NY 10017

Dear Ms. Collins:

Please refer to your supplemental new drug application dated May 30, 2008, received May 30, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Aldactone (spironolactone) 25 mg, 50 mg, and 100 mg Tablets.

This supplemental application provides for your response to the Divisions March 1, 2006 letter with recommendations to revise labeling for Aldactone including a description of the RALES study and revisions to the **INDICATIONS**, **PRECAUTIONS**, **WARNINGS**, and **DOSAGE AND ADMINISTRATION** sections of the labeling. We also note that you made minor editorial changes throughout the label.
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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 content of labeling [21 CFR.314.50(1)] in structured product labeling (SPL) format submitted on May 30, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the structured product labeling (SPL) format submitted on May 30, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 12-151 S-062."

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 Mr. John David, Regulatory Project Manager at (301) 796-1059.
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: enclosed labeling (text for the 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

11/25/2008 08:07:05 AM