DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-437/S-006

Pfizer Global Pharmaceuticals
Attention: Robert Clark
235 East 42nd Street
MS 685/18/03
New York, NY 10017

Dear Mr. Clark:

Please refer to your supplemental new drug application dated April 18, 2008, received April 18, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Inspra (eplerenone) 25 mg and 50 mg Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes in the labeling made to the second paragraph of section 8.4 (Pediatric Use) as requested by the Division in a letter dated March 14, 2008.

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(l)] in structured product labeling (SPL) format submitted on April 18, 2008.

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 John David, Regulatory Health 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

Cc: Enclosed labeling text

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

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