DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-437/S-005

Pfizer Global Pharmaceuticals
Attention: Liza Karpiak, R.Ph., M.S.
235 East 42nd Street
New York, NY 10017

Dear Ms. Karpiak:

Please refer to your supplemental new drug application dated July 31, 2007, received August 1, 2007, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Inspra (eplerenone) 25 mg and 50 mg Tablets.

We acknowledge receipt of your submissions dated September 12 and November 15, 2007.

This supplemental new drug application provides information about the use of Inspra (eplerenone) Tablets for hypertension in pediatric patients.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 enclosed labeling (text for the package insert). 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 sNDA 21-437/S-005."

We note that your January 30, 2008 email submission includes agreed-upon labeling text for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We note that you have fulfilled the pediatric study requirement for ages 2 to 16 years for this application. We are waiving the pediatric study requirement for ages 0 to 2 years because there is evidence strongly suggesting that the drug would be ineffective or unsafe in this pediatric age group. Adverse effects upon hormonal levels observed in adults and older children would expect to be more problematic in younger children.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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: agreed-upon 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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