



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-437

1-132

Pfizer, Inc.
Attention: Mr. John Berryman
235 East 42nd Street
New York, NY 10017

04-10-07A11:46 RCYC

Dear Mr. Berryman:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inspra (eplerenone) 25, 50 & 100 mg Tablets.

The Pediatric Research Equity Act ("PREA") was enacted on December 3, 2003. For applications submitted between April 1, 1999 and December 3, 2003, where pediatric studies were deferred under the regulations in effect at the time the application was submitted, PREA extended the deferral date by a minimum of 411 days. This application was submitted on November 28, 2001 and has a deferral of pediatric studies until August 17, 2004. Under PREA, those studies are now deferred until August 17, 2007.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. The commitment is listed below.

1. Deferred pediatric studies under PREA for the treatment of hypertension in pediatric patients ages 6 to 16 years of age.

Final Report Submission: August 17, 2007

2. Waived pediatric studies under PREA for the treatment of hypertension in pediatric patients ages <1 month to <6 years of age.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Health Project Manager
301-594-5332

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Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Norman Stockbridge
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