DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WRITTEN REQUEST – AMENDMENT #1

NDA 20-998
NDA 21-156
IND 48,395

Pfizer, Inc.
235 E. 42nd Street
New York, NY 10017

Attention: Robert B. Clark
Vice President, US Regulatory

Dear Mr. Clark:

Please refer to your correspondence to IND 48,395, dated November 3, 2005, requesting changes to FDA's January 25, 2002, Written Request for pediatric studies for celecoxib.

We have reviewed your proposed changes and are amending the below-listed section of the Written Request. All other terms stated in our Written Request issued on January 25, 2002, remain the same.

Time frame for submitting reports of the studies:

Study reports should be submitted to the Agency on or before June 30, 2006. Please remember that pediatric exclusivity extends only existing patent protection or exclusivity that has not expired or been previously extended at the time you submit your study report in response to this Written Request.

Reports of the studies that meet the terms of the Written Request dated January 25, 2002, as amended by this letter, must be submitted to the Agency on or before June 30, 2006, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Submit reports of the studies as a supplement to an approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger, to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, call Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at 301-796-1202.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, MD
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Robert Meyer

12/19/2005 11:57:43 AM