DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-088 **WRITTEN REQUEST – AMENDMENT #1**

Wyeth Pharmaceuticals
Attn: Patricia M. Johnson
Director I, Global Regulatory Affairs
87 CambridgePark Drive
Cambridge, MA 02140

Dear Ms. Johnson:

Please refer to your correspondence dated August 13, 2004, requesting changes to FDA's January 12, 2001, Written Request, reissued under the Best Pharmaceuticals for Children Act on September 30, 2004, for pediatric studies for temsirolimus. We also refer to your June 21, 2006, request to amend the Written Request and to the telecommunication between the Agency and Wyeth held on August 4, 2006.

We have reviewed your proposed changes and are amending the timeframe for submitting reports of the studies from on or before October 1, 2007, to on or before September 30, 2010. All other terms stated in our Written Request issued on January 12, 2001, and reissued on September 30, 2004, remain the same.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, **"PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY"** in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, **"PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission.

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 Carl Huntley, R.Ph, MBA, Regulatory Project Manager, at 301-796-1372.

Sincerely yours,

Karen D. Weiss, MD
Deputy Director
Office of Oncology Drug Products
Office of New Drugs
Center for Drug Evaluation and Research

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/s/

Robert Justice
9/28/2007 07:39:20 PM
for Karen Weiss, M.D.