DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND 55830

Wyeth Pharmaceuticals
87 CambridgePark Drive
Cambridge, MA 02140

Attention: Narayan Rao
Senior Manager
Worldwide Regulatory Affairs

Dear Mr. Rao:

Please refer to your correspondence dated February 27, 2003, requesting changes to FDA's January 12, 2001 Written Request, reissued under the Best Pharmaceuticals for Children Act on July 3, 2002, for pediatric studies for CCI-779.

We reviewed your proposed changes and are amending the below listed sections of the Written Request. All other terms stated in our Written Request issued on January 12, 2001, reissued July 3, 2002 remain the same.

The following changes have been made to the original Written Request per your request:

1. Please refer to your Investigational New Drug Application (IND) for (b) (4) (CCI-779), IND #55,830.

   The Food and Drug Administration (FDA) is hereby making a formal Written Request, pursuant to Section 505A of the Federal Food, Drug, and Cosmetic Act (the Act), that you submit specific pediatric studies, detailed later in the letter. These studies investigate the potential use of (b) (4) CCI-779 in the treatment of children with brain tumors or other solid tumors.

2. Reports of the above studies must be submitted to the Agency on or before ~~**December 31, 2003**~~ **October 1, 2007**. Please keep in mind that pediatric exclusivity attaches only to existing patent protection or exclusivity that has not expired at the time you submit your reports of the studies in response to this Written Request.

As stated above, reports of the studies that meet the terms of the Written Request dated January 12, 2001, reissued July 3, 2002, as amended by this letter must be submitted to the Agency on or before **October 1, 2007**, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

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 New Drug Application (NDA) or 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 Sean Bradley, R.Ph., Regulatory Project Manager, at 301-594-5770.

Sincerely,

{See appended electronic signature page}

Rachel E. Behrman, M.D., M.P.H.
Deputy Director
Office of Drug Evaluation 1
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/

Rachel Behrman

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