DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

IND 40,061

Eli Lilly and Company
Attention: John F. Worzalla
Regulatory Research Scientist, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Worzalla:

This letter supersedes the amended pediatric written request letter dated July 9, 2004. The July 9, 2004 letter referenced the incorrect drug product to IND 40,061. This letter contains the corrected information.

Please refer to your correspondence dated March 24, 2004, requesting changes to FDA's October 5, 2001, Written Request for pediatric studies for Alimta® (pemetrexed for injection). We also refer to our July 3, 2002 correspondence that re-issued the October 5, 2001 Written Request under the Best Pharmaceuticals for Children Act and our May 7, 2004 correspondence that amended the Written Request.

We have 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 October 5, 2001, re-issued on July 3, 2002, and amended on May 7, 2004, remain the same.

- *Timeframe for submitting reports of the studies:*

  Reports of the studies that meet the terms of the Written Request dated October 5, 2001, and re-issued July 3, 2002, as amended by this letter, must be submitted to the Agency as part of a new drug application or supplement to an approved new drug application on or before June 30, 2007, in order to qualify for possible 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)** 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 Patty Garvey, Regulatory Project Manager, at 301-594-5766.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
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 Temple

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