DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-462/S-012

Eli Lilly and Company
Attention: Colleen Mockbee, R.Ph., RAC
Manager, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Mockbee:

Please refer to your supplemental new drug application dated May 7, 2007, received May 8, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alimta (pemetrexed for injection).

We acknowledge receipt of your submissions dated September 4 and 6 (electronic), 2007.

This supplemental new drug application provides for a new strength, 100 mg vials.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon enclosed labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert, patient package insert, immediate container and carton labels).

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-462/S-012**." Approval of this submission by FDA is not required before the labeling is used.

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Patricia Garvey, Senior Regulatory Project Manager, at (301) 796-1356.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Robert Justice
9/7/2007 04:50:55 PM