DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-462/S-015

Eli Lilly and Company
Attention: Colleen Mockbee, R.Ph., RAC
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Mockbee:

Please refer to your supplemental new drug application dated August 27, 2007, received August 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alimta® (pemetrexed disodium) Injection, Powder, Lyophilized, For Solution for Intravenous use 100 mg and 500 mg vials.

Please also refer to your submission dated June 24, 2008, received June 24, 2008, which extended the due date for this application to September 28, 2008.

We acknowledge receipt of your submissions dated September 20, October 18, 30, November 19, 2007; February 8, March 19, June 24, and September 11, 16, 18, 19, 20, 22, 23, and 24 (all electronic except the 20th), 2008.

This supplemental new drug application provides for the use of Alimta® (pemetrexed disodium) Injection, Powder, Lyophilized, For Solution for Intravenous use 100 mg and 500 mg vials for the following indications.

Non-Small Cell Lung Cancer — Combination with Cisplatin

ALIMTA is indicated in combination with cisplatin therapy for the initial treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer. ALIMTA is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

Non-Small Cell Lung Cancer — Single Agent

ALIMTA is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. ALIMTA is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

We have completed the review of this supplemental application, as amended, according to the regulations for accelerated approval, and have concluded that adequate information has been presented to approve Alimta® (pemetrexed disodium) Injection, Powder, Lyophilized, For Solution for Intravenous use 100 mg and 500 mg vials for use as recommended in the enclosed labeling text. Accordingly, the application is approved under 21 CFR 314 Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of the referenced accelerated approval regulations.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-462/S-015."

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled studies to verify and describe clinical benefit. We remind you of your post marketing study (Subpart H Phase 4 commitments) specified in your submission dated August 3, 2004. This commitment, along with any completion dates agreed upon, is listed below.

2. H3E-MC-JMEN: Multicenter, Randomized Phase III Study of Maintenance Therapy with Single-Agent Alimta versus Best Supportive Care after Treatment with Gemcitabine plus Carboplatin in Chemo-naive Patients with Advanced Non-Small Cell Lung Cancer.

   Status: Planned number of patients enrolled: 660
   First patient visit: March 2005
   Last patient visit: May 2008
   Final study report: November 2008

   We acknowledge receipt of your submission dated September 15, 2008, which includes a study report for H3E-MC-JMEN (Study JMEN).

Final study reports should be submitted to this NDA as a supplemental application. For administrative purposes, all submissions relating to these Phase 4 commitment**s** must be clearly designated "**Subpart H Phase 4 Commitments**."

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "**Phase 4 Commitments**."

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Carl Huntley, Regulatory Project Manager, at (301) 796-1372**.**

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
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