DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-462/S-018
NDA 21-462/S-021
NDA 21-462/S-022

Eli Lilly and Company
Michael R. Langley, D.V.M., RAC
Associate Director, Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Langley:

Please refer to your supplemental new drug applications dated September 27, 2007, received September 28, 2007, September 15, 2008, received September 16, 2008, and October 13, 2008, received October 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alimta (pemetrexed disodium) Injection, Powder, Lyophilized for Intravenous Use 100 mg and 500 mg vials.

We acknowledge receipt of your submissions dated November 17, 2008; March 25, April 24, May 15, 19 and 26, June 5 and July 2 (electronic), 2009.

S-021 provides for the use of Alimta (pemetrexed disodium) Injection, Powder, Lyophilized for Intravenous Use 100 mg and 500 mg vials in maintenance treatment in patients with advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first line chemotherapy. Alimta is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

S-018 "Changes Being Effected" supplemental new drug application provides for updating the Adverse Reactions: Post-Marketing Experience Section of the Package Insert.

S-022 "Changes Being Effected" supplemental new drug application provides for the addition of General Disorders and Administration Site Conditions – edema to Section 6.2 of the Package Insert.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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, text for the patient 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-018, NDA 21-462/S-021 and NDA 21-462/S-022."

We approved NDA 21-677, NDA 21-462/S-001 and NDA 21-462/S-015 under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of both S-015 and S-021 fulfills your commitments made under 21 CFR 314.510.

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, deferred or inapplicable. We are waiving the pediatric study requirement for this application.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, call Frank Cross, Regulatory Project Manager, at (301) 796-0876.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
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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