DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-509/S-037

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 June 2, 2005, received June 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gemzar® (gemcitabine HCl) for Injection.

This supplemental new drug application provides for safety labeling changes in the Precautions, Post-marketing experience in Adverse Reactions, and Dosage and Administration sections of the package insert.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the labeling text submitted on June 2, 2005.

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

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Patricia Garvey, Regulatory Project Manager, at (301) 796-1356.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Acting 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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