



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-509/S-029

Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

Attention: Thierry Kern  
U.S. Regulatory Affairs, Oncology

Dear Mr. Kern:

Please refer to your supplemental new drug application dated December 17, 2004, received December 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gemzar® (gemcitabine HCl) for Injection.

We acknowledge receipt of your submissions dated January 28 and 29, February 19, March 15 and 25, April 8, May 12 and 13, 2004.

This supplemental new drug application provides for the use of Gemzar® (gemcitabine HCl) for Injection in combination with paclitaxel for the first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.

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 labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 20-509/S-029.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment as agreed in the facsimile dated May 19, 2004. The commitment, along with the completion date agreed upon, is listed below.

Complete study B9E-MC-JHQG (Multi-center, Phase 3 Study of Gemcitabine Plus Paclitaxel Versus Paclitaxel in Patients with Unresectable, Locally Recurrent or Metastatic Breast Cancer). Submit the final analysis of overall survival when the protocol specified number of

deaths for the final analysis have occurred. This analysis should be submitted within 6 months of the date of the last death.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.8(b)(2)(vii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled “**Postmarketing Study Protocol**”, “**Postmarketing Study Final Report**”, or “**Postmarketing Study Correspondence**.”

All application 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.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Oncology Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising and Communcation, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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

MEDWATCH, HFD-410  
FDA  
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 Patty Garvey, Regulatory Project Manager, at (301) 594-5766.

Sincerely,

*{See appended electronic signature page}*

Richard Pazdur, M.D.  
Director  
Division of Oncology Drug Products  
Center for Drug Evaluation and Research

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

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Richard Pazdur  
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