



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020509/S-064

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Guy C. Ruble, Pharm.D.
Associate Manager, US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Ruble:

Please refer to your supplemental new drug application dated June 8, 2009, received June 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gemzar® (gemcitabine HCl) Injection, 1 g., 200 mg.

We acknowledge receipt of your submissions dated January 28, 2010, February 19, 2010, and March 17, 2010.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, 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)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed agreed upon package insert dated February 19, 2010. These revisions are terms of the NDA approval. For administrative purposes, please designate this submission, "SPL for approved NDA 020509/S-064".

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Amy Tilley, Regulatory Project Manager, at 301-796-3994.

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: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-20509	----- SUPPL-64	----- ELI LILLY AND CO	----- GEMZAR

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

/s/

AMNA IBRAHIM
03/19/2010