DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 19 1997

TRANSMITTED VIA FACSIMILE

David R. McAvoy
Eli Lilly and Company
Lilly Corporate Center
Mail Drop Code 1132
Indianapolis, Indiana 46285

RE: **NDA 20-509**
Gemzar (gemcitabine HCl)
MACMIS ID # 5236

Dear Mr. McAvoy:

As part of its routine monitoring and surveillance program, it has come to the attention of the Division of Drug Marketing, Advertising and Communications (DDMAC) that Eli Lilly and Company (Lilly) is promoting Gemzar in a manner that is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specific violations are outlined below.

PROMOTION OF UNAPPROVED USES

DDMAC has obtained evidence that Lilly sales representatives are disseminating materials that promote Gemzar for an unapproved use. Specifically, we refer to an oncology seminar held on Friday, March 7, 1997, at the Bethesda National Naval Medical Center. A Lilly representative disseminated reprints of articles, abstracts, and a summary of published studies, all of which describe the use of Gemzar in non-small cell lung cancer. Promotion of a drug product for uses not approved or permitted for use in labeling is in violation of the Act.

FAILURE TO SUBMIT UNDER FDA FORM 2253

Promotional materials distributed by the above referenced sales representative were not submitted to FDA pursuant to post-marketing reporting requirements for promotional labeling and advertising, 21 CFR §314.81(b)(3)(I).

In order to address these violations, DDMAC recommends that Lilly take the following actions:

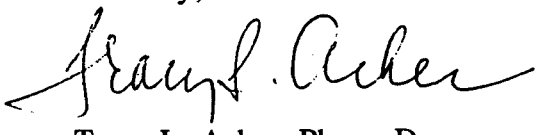
1. Immediately discontinue the use of any and all promotional materials that promote Gemzar for an unapproved use.

2. Provide FDA with a list and copies of any and all other promotional materials in use by Lilly sales representatives that have not been submitted to FDA pursuant to 21 CFR §314.81 (b)(3)(I).

3. Provide to DDMAC in writing Lilly's intent to comply with items 1 and 2 above. Lilly should respond on or before April 2, 1997, to the undersigned at the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane, HFD-40, Rockville, Maryland 20857. DDMAC reminds Lilly that only written communication is considered official.

In all correspondence regarding this particular issue, please refer to MACMIS ID# 5236 in addition to the NDA number.

Sincerely,



Tracy L. Acker, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

File Name: C:\WPFILES\GEMZAR\NAVAL.REP

Drafted: Acker 3/14/97
Concur: Abrams 3/19/97

CC:
HFD-40/NDA # 20-509
HFD-40/Chron/Acker/Abrams
HFD-150/NDA # 20-509
HFD-150/McCollum/Schechter/Kobayashi

MACMIS ID # 5236

MACMIS Type Code:LETT
MACMIS Action Code:viol

Due Date: April 2, 1997

Close Out: N

FOI STATUS: RELEASABLE