DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-509/S-021

Eli Lilly and Company
Attention: Elizabeth Sloan, Ph.D., [DC 2546]
Director Oncology, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Sloan:

Please refer to your supplemental new drug application dated October 24, 2001, received October 25, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gemzar (gemcitabine HCl) for injection

We acknowledge receipt of your submission dated October 24, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the modification for the(b)(4)----------.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Debra Vause, B.S.N., Regulatory Project Manager, at (301) 594-5724.

Sincerely,

{See appended electronic signature page}

Richard Lostritto, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Oncology Drug Products, (HFD-150)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

/s/

Richard Lostritto

5/1/02 04:41:58 PM