DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Memorandum

Date: June 30, 2004

To: Oncologic Drugs Advisory Committee Members and Guests

From: Richard Pazdur, M.D.
Director, Division of Oncology Drug Products, CDER, FDA

Subject: FDA Background Package for July 27 ODAC Meeting

The Division of Oncology Drug Products has chosen to convene a session of the Oncologic Drugs Advisory Committee on July 27th to seek your assistance and advice on an oncology drug product. We have provided this background package in order to assist you in your discussion. It includes documents that review the application related to both clinical and statistical data.

Documents in this background package include:

FDA Clinical Review:

TAB 1 Cinical Review of NDA 21-677 Alimta (pemetrexed), Eli Lilly & Co.

FDA Statistical Review:

TAB 2 Statistical Review of NDA 21-677 Alimta (pemetrexed), Eli Lilly & Co.

We greatly appreciate your participation in this discussion and look forward to seeing you in July.