DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103795/5229

JUL 28 2005

Amgen, Inc.
Attention: John S. Walker
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Mr. Walker:

Your request to supplement your biologics license application for Etanercept to revise the Warnings, Adverse Reactions, and the Drug Interactions sections of the package insert (PI) regarding non-cutaneous malignancies in Wegener's Granulomatosis patients treated with both Etanercept and standard therapy, and to revise the Patient Package Insert (PPI) to recommend that Etanercept and cyclophosphamides not be given concurrently, has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder biologics/default.htm for important information regarding therapeutic biological products, including the address for submissions Effective Oct 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

This information will be included in your biologics license application file.

Sincerely,

Marc K. Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research