DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103795/5051

SEP 12 2002

Sally Gould
Immunex Corporation
51 University Street
Seattle, WA 98101-2936

Dear Ms. Gould:

Your request to supplement your biologics license application for Etanercept to revise the Clinical Studies and Adverse Reactions sections of the package insert to reflect three-year safety and efficacy information in rheumatoid arthritis patients has been approved.

We acknowledge that you have fulfilled post-marketing commitment number 15 identified in the November 2, 1998 approval letter for Etanercept.

We also acknowledge that you have submitted the data to address the three-year reporting milestone in your post-marketing commitment number 2, identified in the June 6, 2000 approval letter for Etanercept. Long-term data on the development of cancer and autoimmune diseases for all patients enrolled in protocols 16.0018 and 16.0023 at the five and ten-year time points have not been submitted; thus this commitment remains open and you will need to continue to report on this commitment in your Postmarketing Commitment Annual Report.

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). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

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

Sincerely yours,

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research