DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

BLA 103795/5565

APPROVAL LETTER

Immunex Corporation, a wholly-owned
subsidiary of Amgen, Inc.
Attention: Tabetha Bonacci, Ph.D.
Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320

Dear Dr. Bonacci:

Please refer to your Supplemental Biologics License Application (sBLA) dated November 13, 2017, received November 13, 2017, submitted under section 351(a) of the Public Health Service Act for Enbrel (etanercept).

This "Changes Being Effected in 30 days" supplemental biologics application proposes the following labeling changes: (1) change to the strength/volume of the SureClick carton and container labels, (2) addition of room temperature storage information/instructions to the cartons of the Pre-filled Syringe and SureClick autoinjector.

We have completed our review of this supplemental biologics application. This supplement is approved.

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

If you have any questions, call Andrew Shiber, Regulatory Project Manager, at (301) 796-4798.

Sincerely,

{See appended electronic signature page}

Kathleen A. Clouse, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research