DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125276/S-106
BLA 125472/S-014

SUPPLEMENT APPROVAL

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080-4990

Attention: John Bergan
Regulatory Program Management

Dear Mr. Bergan:

Please refer to your Supplemental Biologics License Applications (sBLAs) dated and received June 26, 2015, submitted under section 351(a) of the Public Health Service Act for BLA 125276/S-106, Actemra (tocilizumab) Injection for intravenous use, 80 mg/4 mL, 200 mg/10 mL, and 400 mg/ 20 mL and BLA 125472/S-014, Actemra (tocilizumab) Injection for subcutaneous use, 162 mg/0.9 mL.

These prior approval supplemental biologics applications propose to eliminate the requirement for the approved risk evaluation and mitigation strategy (REMS) for Actemra. These supplements are in response to our May 29, 2015, REMS Modification Notification letter.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Actemra (tocilizumab) Injection was originally approved on January 8, 2010, and the most recent REMS modification was approved on October 21, 2013. The approved REMS consists of a communication plan and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modification: propose to eliminate the requirement for the REMS. Because the communication plan has been completed and the most recent assessment, submitted to the Agency on December 22, 2014, demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Actemra (tocilizumab).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Carol F. Hill, Senior Regulatory Health Project Manager for Safety, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
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/

SALLY M SEYMOUR
08/18/2015