DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125276/75

SUPPLEMENT APPROVAL
REMS MODIFICATION APPROVAL
REMS ASSESSMENT ACKNOWLEDGEMENT

Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080

Attention: Stuart Heminway
Program Director, Regulatory Affairs

Dear Mr. Heminway:

Please refer to your Supplemental Biologics License Application (sBLA), dated January 3, 2013 and received January 4, 2013, submitted under section 351(a) of the Public Health Service Act for Actemra (tocilizumab).

We acknowledge receipt of your amendments dated April 3, May 6, and June 28, 2013, and your risk evaluation and mitigation strategy (REMS) assessment dated January 3, 2013.

This Prior Approval supplemental biologics application provides for proposed modifications to the approved REMS to clarify the laboratory abnormality information in the Prescriber Education Slide Deck.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter. In addition we have found the REMS assessment to be complete.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Actemra (tocilizumab) was originally approved on January 8, 2010, and REMS modifications were approved on April 15, 2011, June 20, 2012, October 11, 2012, and last modified on April 29, 2013. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of a revised Prescriber Education Slide Deck in the Communication Plan.

Your proposed modified REMS, submitted on June 28, 2013, and appended to this letter, is approved.

The timetable for submission of assessment of the REMS will remain the same as that approved on January 8, 2010.

There are no changes to the REMS assessment plan described in our June 20, 2012, letter.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

BLA 125276 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

BLA 125276 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125276
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125276
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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 Philantha Bowen, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
REMS

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
07/02/2013