



BLA 125472/S-038  
BLA 125276/S-125

## SUPPLEMENT APPROVAL

Genentech, Inc.  
1 DNA Way  
Bldg 35, MS 5F  
South San Francisco, CA 94080

Attention: Michael Woods  
Regulatory Program Management

Dear Mr. Woods:

Please refer to your Supplemental Biologics License Application (sBLA), dated November 5, 2018, received November 5, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for Actemra (tocilizumab) injection, 162 mg/0.9 mL for subcutaneous administration, and sBLA dated November 2, 2018, received November 2, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for Actemra (tocilizumab) injection, 80 mg/4 mL, 200 mg/10 mL, or 400 mg/20 mL for intravenous infusion.

These “Changes Being Effected” supplemental biologics application provide for the addition of “fibrinogen” in Section 12.2, addition of “GCA” in Section 2.9, and inclusion of NCT numbers and Study numbers in Section 14.

### **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

### **WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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.

### **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 Elaine Sit, Regulatory Project Manager, at (301) 796-5073.

Sincerely,

*{See appended electronic signature page}*

Sally Seymour, MD  
Acting Director

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Division of Pulmonary, Allergy, and Rheumatology  
Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

**ENCLOSURE(S):**

Content of Labeling

Prescribing Information

Medication Guide

Instructions for Use

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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SALLY M SEYMOUR  
12/20/2018