



BLA 125472/S-058
BLA 125276/S-146

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Dhushy Thambipillai
Regulatory Project Management
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dhushy Thambipillai:

Please refer to your supplemental biologics license applications (sBLAs), dated and received June 10, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Actemra (tocilizumab) for subcutaneous and intravenous injection.

Prior Approval supplemental biologics application BLA 125472/S-058 provides for updates to the pictogram on the Medication Guide (MG)/Instructions-for-Use (IFU) leaflet for ACTPen (autoinjector).

Prior Approval supplemental biologics application BLA 125276/S-146 provides for alignment of the labeling for the two routes of administration.

APPROVAL & LABELING

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

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

FDA.gov,¹ 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 *SPL Standard for Content of Labeling Technical Qs and As*.²

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 supplement applications, 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).

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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If you have any questions, contact Susie Choi, Regulatory Project Manager, at susie.choi@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Hyon Kwon, PharmD, MPH
Deputy Director for Safety
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information (approved September 2024)
 - Medication Guide (approved September 2024)
 - Instructions for Use
 - Prefilled syringe (approved September 2024)
 - Autoinjector (approved September 2024)
 - Pictogram

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.

/s/

HYON J KWON
12/10/2024 01:26:15 PM