BLA 125276/S-149

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

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

Dear Dhushy Thambipillai:

Please refer to your supplemental biologics license application (sBLA) received October 9, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Actemra (tocilizumab) injection for intravenous use.

This Prior Approval supplemental biologics license application for Actemra (tocilizumab) provides for the expansion of the COVID-19 indication for the treatment of hospitalized patients aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

This supplement provides for pediatric labeling text pursuant to the Pediatric Research Equity Act (PREA). This approval is in response to a PREA PMR.

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 Effected” (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 Effected" (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.

The pediatric study requirement for children less than 1 year of age was previously waived with the December 21, 2022, approval of BLA 125276/S-138. We are also waiving the pediatric study requirement for ages 1 to 2 years because necessary studies are impossible or highly impracticable. This is because the number of patients is so small and the patients are geographically dispersed.

We note that you have fulfilled the pediatric study requirement for ages 2 to 17 years for this application.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated October 9, 2024, containing the final report for the following postmarketing requirement listed in the December 21, 2022, approval letter for BLA 125276/S-138.

PMR 4369-1: Conduct a pharmacokinetic, pharmacodynamic, and safety study in pediatric patients hospitalized with COVID-19

[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.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there is a postmarketing requirement listed in the February 26, 2020, post-approval postmarketing requirement letter that is still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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, contact Nina Ton, Senior Regulatory Project Manager, at (301) 796-1648 or phuong.ton@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Banu Karimi-Shah, MD
Acting Division Director
Division of Pulmonology, Allergy,
and Critical Care
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information
    - Medication Guide
    - Instructions for Use

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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/

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