BLA 761275/S-022

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Fresenius Kabi USA, LLC
Attention: Carole Youmbi
Director, Regulatory Affairs
Three Corporate Drive
Lake Zurich, IL 60047

Dear Carole Youmbi:

Please refer to your supplemental biologics license application (sBLA) received November 25, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Tyenne (tocilizumab-aazg) injection.

This Category D Prior Approval supplemental BLA provides for expansion of the Coronavirus disease 2019 (COVID-19) indication to include hospitalized pediatric patients aged 2 years and older with 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.

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 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.

At this time, we have determined that no pediatric assessment will be required under PREA for patients 0 to <2 years of age. You have provided a pediatric assessment for COVID-19 in pediatric patients 2 years of age and older, and nothing further is required under PREA for BLA 761275/S-022.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated November 25, 2025, containing the final report for the following postmarketing requirement listed in the February 28, 2025, approval letter for BLA 761275/S-008.

PMR 4806-1 Assessment of Tyenne (tocilizumab-aazg) for the treatment of COVID-19 in pediatric patients 1 to <18 years of age.

Final Report Submission: 06/2026

We have reviewed your submission and conclude that you have fulfilled the PREA requirement for COVID-19 in pediatric patients.

[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.

This closes your postmarketing requirement acknowledged in our February 28, 2025, letter. You are not required to report on the status of closed (released or fulfilled) PMR in your annual report required under 21 CFR 601.70.

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 Chau Nguyen, Regulatory Project Manager at chau.nguyen@fda.hhs.gov or (240)-402-0022.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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/

BANU A KARIMI SHAH
05/20/2026 03:54:57 PM