BLA 761354/S-009

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Organon LLC
Attention: Swarna Dhavala
Director, Regulatory Liaison
30 Hudson Street
33rd Floor
Jersey City, NJ 07302

Dear Swarna Dhavala:

Please refer to your supplemental biologics license application (sBLA) received December 4, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Tofidence (tocilizumab-bavi) injection.

This Category D Prior Approval supplemental biologics license application provides for the addition of the following indications:

- Cytokine Release Syndrome (CRS)
  - The treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.

- Coronavirus Disease 2019 (COVID-19)
  - The treatment of coronavirus disease 2019 (COVID-19) in hospitalized pediatric patients aged 2 years and older 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.

Information on submitting SPL files using eLIST may be found in 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.

- Cytokine Release Syndrome (CRS)
  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 CRS in pediatric patients 2 years of age and older, and nothing further is required under PREA for CRS in pediatric patients.

- Coronavirus Disease 2019 (COVID-19)
  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 COVID-19 in pediatric patients.

[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.

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

We have received your submission dated December 4, 2025, containing the final report for the following postmarketing requirement listed in the July 22, 2024 approval letter for BLA 761354/S-002:

PMR 4664-1: Assessment of Tofidence (tocilizumab-bavi) for the treatment of COVID-19 in pediatric patients 1 year to <18 years of age.

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

This closes your postmarketing requirement acknowledged in our July 22, 2024, letter. You are not required to report on the status of closed (released or fulfilled) PMRs/PMC in your annual report required under 21 CFR 601.70.

PROMOTIONAL MATERIALS

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

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.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 601.12(f)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(f)(4).

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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).

You may contact Anh-Thy Ly, Regulatory Project Manager, at 240-402-1001 or Anh-Thy.Ly@fda.hhs.gov if you have any additional questions.

Sincerely,

{See appended electronic signature page}

Kelly Norsworthy, MD
Division Director
Division of Hematologic Malignancies I
Office of Oncologic Diseases
Office of New Drugs
Center for Drug Evaluation and Research

Banu Karimi Shah, MD
Division Director
Division of Pulmonology, Allergy, and 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/

KELLY J NORSWORTHY
05/22/2026 09:09:04 AM

BANU A KARIMI SHAH
05/22/2026 09:30:37 AM