BLA 761344/S-002

SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Caroline Lilley, PhD
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320

Dear Dr. Lilley:

Please refer to your supplemental biologics license application (sBLA) received March 13, 2026, and your amendments, submitted under section 351(a) of the Public Health Service Act for Imdelltra (tarlatamab-dlle) injection.

This Prior Approval sBLA provides for updates to the cytokine release syndrome monitoring in the U.S. Prescribing Information labeling for tarlatamab infusions.

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 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.

[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.

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.

Because none of these criteria apply to your supplement 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).

REQUESTED ENHANCED PHARMACOVIGILANCE (EPV)

We request that for IMDELLTRA, you continue to submit all U.S. cases describing adverse reactions that may be cytotoxic release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) as 15-day "Alert reports" (described under 21 CFR 600.80(c)(1)) through the second year following U.S. approval of supplement 002.

We request that you continue to provide a separate narrative summary and analysis for cases that may be ICANS or CRS, involving IMDELLTRA, in each required postmarketing periodic safety report (e.g., Periodic Adverse Experience Report [PAER] required under 21 CFR 600.80(c)(2)).

Your narrative summary and analysis should include an interval and cumulative assessment of each event and a line listing of the cases for the reporting interval. Your narrative summary should include an assessment of the following:

- The number of cases reporting a patient who experienced an event that may be CRS or ICANS involving IMDELLTRA.

- Action taken in response to an event that may be CRS or ICANS involving IMDELLTRA, including but not limited to hospitalization status, treatments administered, and supportive care.
- Outcome of an event that may be CRS or ICANS involving IMDELLTRA.
- Outcome of retreatment after event that may be CRS or ICANS involving IMDELLTRA if applicable (including prior medications given and dose received).

If you have any questions, contact Ashley Lane, Senior Regulatory Health Project Manager, at Ashley.Lane@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Erin Larkins, M.D.
Director
Division of Oncology 2
Office of Oncologic Diseases
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/

ERIN A LARKINS
09/11/2026 01:00:15 PM