BLA 761285/S-004
BLA 761331/S-004

SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Augustus Kamassah
Director, Global Biosimilars Regulatory Affairs
One Amgen Center Drive
Mail Stop: 28-4A
Thousand Oaks, CA 91320

Dear Augustus Kamassah:

Please refer to your supplemental biologics license applications (sBLAs) received March 26, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for the following:

Application Number	Product Name	Date of Submission	Date of Receipt
BLA-761285-SUPPL-4	Wezlana (ustekinumab-auub) injection	March 26, 2025	March 26, 2025
BLA-761331-SUPPL-4	Wezlana (ustekinumab-auub) injection	March 26, 2025	March 26, 2025

These Prior Approval supplemental biologics applications provide for:

- Updated branded labeling to align with recent changes to the labeling for US-licensed Stelara approved June 27, 2025.

- Unbranded biological product labeling for Ustekinumab-auub,
  - For subcutaneous use:
    - 45 mg/0.5 mL and 90 mg/mL PFS
    - 45 mg/0.5 mL vial
    - 45 mg/0.5 mL and 90 mg/mL prefilled AI
  - For intravenous infusion:
    - 130 mg/26 mL vial

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.

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.

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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed**

[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.

Carton and Container Labeling for approved BLA 761285/S-004 and BLA 761331/S-004." Approval of this submission by FDA is not required before the labeling is used.

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 studies will be required under PREA for your sBLAs.

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).

Your products are Part 3 combination products (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have questions, contact Anh-Thy Ly, Project Manager, at 240-402-1001 or Anh-Thy.Ly@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Branded Product Labeling
    - Prescribing Information
    - Medication Guide
    - Instructions for Use
  - Unbranded Biological Product Labeling
    - Prescribing Information
    - Medication Guide
    - Instructions for Use
    - Carton and Container Labeling

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/

TATIANA OUSSOVA
09/25/2025 05:48:00 PM