

BLA 761285/S-006  
BLA 761331/S-006

## SUPPLEMENT APPROVAL

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

Dear Augustus Kamassah:

Please refer to your supplemental biologics license applications (sBLAs) received February 12, 2026, 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-6	Wezlana (ustekinumab-auub) injection	February 12, 2026	February 12, 2026
BLA-761331-SUPPL-6	Wezlana (ustekinumab-auub) injection	February 12, 2026	February 12, 2026

These Category A supplemental biologics license applications provide for the following changes for Wezlana (ustekinumab-auub) labeling:

- USPI
  - Section 5.5 (Hypersensitivity Reactions)
  - Section 6.3 (Postmarketing Experience)
  - Section 17 (Patient Counseling Information)
- Medication Guide
  - Serious allergic reactions
- IFU
  - Minor edits to improve readability

## **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,<sup>1</sup> 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 Effectuated” (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*.<sup>2</sup>

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 Effectuated” (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).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

## **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.

## **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.<sup>3</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>4</sup>

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).

## **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 product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination

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<sup>3</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at [FDA.gov](http://FDA.gov).

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

ENCLOSURES:

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

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**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.**  
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/s/  
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