



BLA 761343/S-012

SUPPLEMENT APPROVAL

Alvotech USA Inc.
c/o Cencora Global Consulting Services US Corporation
Attention: Anusha Kesireddy
Manager Regulatory Affairs
1 West 1st Avenue
Conshohocken, PA 19428

Dear Anusha Kesireddy:

Please refer to your supplemental biologics license application (sBLA) dated and received June 27, 2025, and your amendment, submitted under section 351(k) of the Public Health Service Act for Selarsdi (ustekinumab-aekn) injection.

This Prior Approval sBLA provides for the following updates to the branded and unbranded product labeling:

1. Updates to the carton labeling and the US Prescribing Information (USPI) Section 16. HOW SUPPLIED/STORAGE AND HANDLING > Storage and Stability, to include that 130mg/26mL vials may be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 7 days, in the original carton to protect from light.
2. Updates to USPI Section 2, Table 2, to remove trailing zeros to minimize 10-fold misinterpretation and dose error if the decimal point goes unnoticed.

APPROVAL & LABELING

We have completed our review of this sBLA, 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](https://www.fda.gov/fda.gov)¹, that is identical to the enclosed labeling (text for the prescribing information) 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at [http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf).

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 MS Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission, 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 LABELS

We acknowledge your September 30, 2025, submission containing final printed carton and container labeling.

This information will be included in your biologics license application file.

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 Musse Olani, Pharm.D., Regulatory Business Process Manager, at musse.olani@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Yan Wang, Ph.D., Supervisor

For:

Ashutosh Rao, Ph.D.

Director

Division of Product Quality Assessment XIV

Office of Product Quality Assessment III

Office of Pharmaceutical Quality

Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling

Carton and Container Labeling



Yan
Wang
(OPQ/OBP)

Digitally signed by Yan Wang (OPQ/OBP)
Date: 11/19/2025 01:23:33PM
GUID: 508da7420002bb89a21873bfe63d2afd