BLA 125261-S171
BLA 761044-S019

SUPPLEMENT APPROVAL

Janssen Biotech, Inc.
Attention: Matthew Phillips
Associate Director
800 Ridgeview Drive
Horsham, PA 19044

Dear Matthew Phillips:

Please refer to your supplemental biologics license application (sBLA) received May 9, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Stelara (ustekinumab) injection.

This Prior Approval supplemental biologics application provides for updates to the subsections *Hypersensitivity Reactions* in the WARNINGS AND PRECAUTIONS, Section 5.5 and *Postmarketing Experience* in the ADVERSE REACTIONS, Section 6.3 of the Prescribing Information to describe serious hypersensitivity reactions, including some reported during the first intravenous dose.

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 with minor editorial revisions listed below and reflected in the enclosed labeling:

- Updated the approval month in Recent Major Changes and at the end of Highlights of the Prescribing Information
- Updated the approval month at the end of the Medication Guide.

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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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).

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 Jay Fajiculay, Senior Regulatory Project Manager, at jay.fajiculay@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology (DG)
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

ENCLOSURE(S):

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

[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.

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/

JOYCE A KORVICK
11/03/2025 04:44:10 PM