BLA 761086/S-013

SUPPLEMENT APPROVAL

Amgen Inc.
Augustus Kamassah, MS
Director, Global Biosimilars Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320

Dear Augustus Kamassah:

Please refer to your supplemental biologics license application (sBLA) received May 30, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Avsola (infliximab-axxq) injection.

This Category A Prior Approval supplemental biologics license application provides for revisions to Section 6.3 (Postmarketing Experience of Adverse Reactions) of the US Prescribing Information (USPI) and revisions to the Avsola Medication Guide to add the Amgen logo, the tradename, and drug name to align with the Avsola USPI.

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.

- In Section 6.1, "Other Adverse Reactions in Adults" of the USPI, we moved the placement of the word "of" from before "patients" to before "infliximab-treated" in the following statement: "…which occurred in 26% of infliximab-treated patients with CD."

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).

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 sBLA.

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).

[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.

If you have questions, call Tiffany Pfundt, Regulatory Project Manager, at (301) 796-1790, or email at tiffany.pfundt@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Raj Nair, MD
Division Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

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/

RAJ NAIR
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