BLA 761024/S-023

SUPPLEMENT APPROVAL

Amgen, Inc.
Attention: Augustus Kamassah, MS
Director, Global Biosimilars Regulatory Affairs
One Amgen Center Drive
Mail Stop 28-4A
Thousand Oaks, CA 91320-1799

Dear Augustus Kamassah:

Please refer to your supplemental biologics license application (sBLA), dated and received October 20, 2023, and your amendments, submitted under section 351(k) of the Public Health Service (PHS) Act for Amjevita (adalimumab-atto) injection.

We acknowledge receipt of your amendment dated January 31, 2025, which constituted a request for approval.

This Prior Approval supplemental biologics license application seeks licensure of Amjevita (adalimumab-atto) injection for subcutaneous use as interchangeable with US-licensed Humira (adalimumab) injection for subcutaneous use as follows:

- Amjevita 80 mg/0.8 mL in a prefilled autoinjector as interchangeable with US-Humira 80 mg/0.8 mL in a prefilled pen,
- Amjevita 80 mg/0.8 mL in a prefilled syringe (PFS) as interchangeable with US-Humira 80 mg/0.8 mL in a PFS,

(b) (4)

- Amjevita 20 mg/0.2 mL in a PFS as interchangeable with US-Humira 20 mg/0.2 mL in a PFS.

For administrative purposes, we have split S (b) (4) into the following supplements:

(b) (4)

- BLA 761024/S-023 – Amjevita (adalimumab-atto) 80 mg/0.8 mL in a prefilled autoinjector and PFS, 20 mg/0.2 mL in a PFS

The subject of this correspondence is BLA 761024/S-023. (b) (4) (b) (4)

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.

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).

[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.

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, no pediatric assessments will be required under PREA for this sBLA. We remind you that postmarketing requirement 3125-3 listed in the September 21, 2016, approval letter is still required.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

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.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, please contact Wendy Streight, PhD, Senior Project Manager, at 240-402-6498 or Wendy.Streight@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling
- Prescribing Information
- Medication Guide
- Instructions for Use

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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