BLA 761299/S-013
BLA 761299/S-020

SUPPLEMENT APPROVAL

Alvotech USA Inc.
c/o PharmaLex US Corporation
c/o Cencora
Attention: Vandan Patel
Senior Specialist, Regulatory Affairs
1 West 1st Avenue
Conshohocken, PA 19428

Dear Vandan Patel:

Please refer to your supplemental biologics license applications (sBLAs) received February 26, 2024, and October 15, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Simlandi (adalimumab-ryvk) injection.

We acknowledge receipt of your amendments dated March 27, 2025, and April 2, 2025, which constituted a request for approval.

These Prior Approval supplemental biologics license applications seek licensure of Simlandi (adalimumab-ryvk) as interchangeable with US-licensed Humira (adalimumab) as follows:

- Supplement 013:
  - Simlandi 20 mg/0.2 mL injection for subcutaneous use in a pre-filled syringe (PFS) as interchangeable with US-Humira 20 mg/0.2 mL injection for subcutaneous use in a PFS.
  - Simlandi 80 mg/0.8 mL injection for subcutaneous use in a PFS as interchangeable with US-Humira 80 mg/0.8 mL injection for subcutaneous use in a PFS.
- Supplement 020:
  - Simlandi 80 mg/0.8 mL injection for subcutaneous use in an autoinjector (AI) as interchangeable with US- Humira 80 mg/0.8 mL injection for subcutaneous use in a prefilled pen.

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,[1] that is identical to the enclosed labeling (text for the Prescribing Information, , Instructions for Use, Medication Guide, and Quick Reference 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).

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 BLA 761299/S-013 or BLA 761299/S-020. We remind you that there are postmarketing requirements listed in the June 26, 2024, and February 14, 2025, approval letters that are still open.

[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.

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.

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
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
  - Quick Reference Guide

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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