BLA 761279/s-005

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Yaa Owuso-Addo, Pharm D
Manager, Global Regulatory Affairs – Americas Regional Regulatory Scientist
Lilly Corporate Center
Drop Code 2543
Indianapolis, IND 46285

Dear Dr. Owusi-Addo:

Please refer to your supplemental biologics license application (sBLA) received April 7, 2025, submitted under section 351(a) of the Public Health Service Act for Omvoh (mirikizumab-mrkz) injection.

This Prior Approval supplemental biologics application provides for the 200 mg/2 mL prefilled pen and 200 mg/2 mL prefilled syringe for use in subcutaneous maintenance dosing for the treatment of moderately to severely active ulcerative colitis in adults.

APPROVAL

We have completed our review of this sBLA, as amended. This supplement is approved with minor editorial revisions listed below and reflected in the enclosed labeling:

- Updated the revision date at the end of the Medication Guide to the approval date
- Added the approval date to the end of the Instructions for Use (IFU) for the 100 mg/mL and 200 mg/2 mL prefilled pen, and the IFU for the 100 mg/mL and 200 mg/ 2 mL prefilled syringe
- Add a space between “200” and “mg” on the lower part of the carton principal display panel for the 200 mg/mL prefilled pen and 200 mg/2 mL prefilled syringe (i.e., “This carton contains a total dose of 200 mg. Once one injection is required for a full dose”).

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 (Prescribing Information, Instructions

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

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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted October 23, 2025, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761279/S-005**." Approval of this submission by FDA is not required before the labeling is used.

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.

Because none of these criteria apply to your supplement application, you are exempt from this requirement.

[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, contact Andrew Chi, PharmD, Regulatory Project Manager, at (301) 796-8597 or email at andrew.chi@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Jessica J. Lee, MD, MMSc
Director
Division of Gastroenterology
Office of Immunology and Inflammation
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/

JESSICA J LEE
10/23/2025 06:41:00 PM