

BLA 761286/S-007

## SUPPLEMENT APPROVAL

UCB, Inc.  
Attention: Robert McNeill, PhD, RAC  
Regulatory Affairs Lead  
4000 Paramount Parkway, Suite 200  
Morrisville, NC 27560

Dear Dr. McNeill:

Please refer to your supplemental biologics license application (sBLA) received June 13, 2025, submitted under section 351(a) of the Public Health Service Act for Rystiggo (rozanolixizumab-noli) injection, for subcutaneous use.

This Prior Approval supplemental biologics application provides for labeling changes in the Prescribing Information to Section 8.1 Pregnancy to add language regarding the pregnancy exposure registry and reference to this registry in Section 17 Patient Counseling Information and addition of Section 6.2 Postmarketing Experience to include "herpes zoster".

### **APPROVAL & LABELING**

We have completed our review of this application. 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,<sup>1</sup> that is identical to the enclosed labeling (Prescribing Information) 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*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

---

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

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 Jemini Patel, Regulatory Project Manager, at [jemini.patel@fda.hhs.gov](mailto:jemini.patel@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Julie Goldrich, MD  
Deputy Director for Safety  
Division of Neurology 1  
Office of Neuroscience  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

-----  
**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/  
-----

JULIE W GOLDRICH  
12/09/2025 01:05:48 PM