DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Karen Mardis
UCB, Inc.
1950 Lake Park Drive
Smyrna, GA 30080

RE: BLA 761286
RYSTIGGO® (rozanolixizumab-noli) injection, for subcutaneous use
MA 286

Dear Karen Mardis:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communications, the landing page, and the "Efficacy" and "Study Design" webpages[1] of the healthcare provider website (US-RZ-2500157) (webpages) for RYSTIGGO® (rozanolixizumab-noli) injection, for subcutaneous use (Rystiggo) submitted by UCB, Inc. (UCB) under cover of Form FDA 2253. FDA has determined that the webpages are false or misleading. Thus, the webpages misbrand Rystiggo and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The landing page of the website for Rystiggo includes the claims "RAPID EFFICACY IN ACTION" and ". . . with improvements observed as early as Week 1," in conjunction with an animated graphic of a man with a normal gait who is walking unassisted up a floating staircase with no railing.

The "Efficacy" webpage, under the "Efficacy & Safety" sub-navigation menu of the website for Rystiggo includes an animated graphic of two women, with normal gait, walking in a crosswalk while one holds a coffee cup in one hand.

The "Study Design" webpage, under the "Efficacy & Safety" sub-navigation menu of the website for Rystiggo includes an animated graphic of a man riding a bike on the street.

These claims and presentations, including the animated graphics of characters moving without any impairment, are not consistent with the presentation of mild generalized myasthenia gravis (gMG) symptoms and misleadingly suggest that Rystiggo provides a greater magnitude of benefit in the treatment of gMG than has been demonstrated. According to the CLINICAL STUDIES section of the FDA-approved prescribing information (PI), the efficacy of Rystiggo was established in a multicenter, randomized, double-blind, placebo-controlled study that enrolled 200 patients. The efficacy of Rystiggo was measured using the Myasthenia Gravis-Activities of Daily Living (MG-ADL) scale, which assesses the impact of gMG on daily functions of 8 signs or symptoms that are typically affected in gMG. The

[1] Landing page located at www.rystiggohcp.com, "Efficacy" webpage located at www.rystiggohcp.com/clinical-trial and "Study Design" webpage located at www.rystiggohcp.com/study-design (last accessed 09.08.2025).

primary efficacy endpoint was the comparison of the change from baseline between treatment groups in the MG-ADL total score at day 43. A statistically significant difference favoring Rystiggo was observed in the MG-ADL total score change from baseline [-3.4 points in the Rystiggo-treated group at either dose vs -0.8 points in the placebo-treated group ($p<0.001$)]. We acknowledge that Figure 1 in the PI shows a separation at day 8 in the mean change from baseline for the Rystiggo and placebo-treated group; however, this change was minimal and not significant at day 8. Therefore, these results do not correlate with the "rapid" and near-complete resolution of gMG symptoms portrayed by the claims and presentations.

Conclusion and Requested Action

For the reasons described above, the webpages misbrand Rystiggo and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that UCB take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above). Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Rystiggo that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Rystiggo.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 286 in addition to the BLA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6.

Additionally, the response submission should be coded as an Amendment to eCTD Sequence 5283 under BLA 761286. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

George Tidmarsh, M.D., Ph.D.
Director
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/

CARTER M BEACH
09/09/2025 05:14:01 PM
On behalf of George Tidmarsh, M.D., Ph.D