DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Kimberly Seay
UCB, Inc.
1950 Lake Park Drive
Smyrna, GA 30080

RE: BLA 761151
BIMZELX® (bimekizumab-bkzx) injection, for subcutaneous use
MA 310

Dear Kimberly Seay:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer broadcast advertisement "Fade Cut" (US-BK-2401669) (TV ad) for BIMZELX® (bimekizumab-bkzx) injection, for subcutaneous use (Bimzelx) submitted by UCB, Inc. (UCB) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Bimzelx and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes the following claims and presentations (emphasis original):

- "I was known for showing up and showing out, … But psoriasis shut me down." (VO, frames 1-2)
- "With Bimzelx, I can't wait to say … I'm back." (VO, frames 4-5)
- "Bimzelx can deliver transformative relief." (VO, frame 7)
- "*Bimzelx* (logo) CAN DELIVER **TRANSFORMATIVE RELIEF**" (on-screen text, frame 7)
- "I'm back to liking what I see looking back at me." (VO, frame 10)
- "Give yourself a chance to say … I'm back." (VO, frames 14-15)
- "**I'm Back**" (on-screen text, frames 5, 10, and 15)

The TV ad begins with scenes of the patient, by himself, reminiscing over pictures of past social interactions and looking concerned about the current appearance of his face, in conjunction with the on-screen text on frame two, "MODERATE-TO-SEVERE ***plaque psoriasis***" (emphasis original). After the introduction of Bimzelx on frame four, the patient is shown smiling and getting "back" to enjoying various social interactions (e.g., at the barber, hanging out with friends, and taking selfies) after experiencing "transformative relief" with Bimzelx.

The totality of these claims and representations misleadingly suggests that Bimzelx has a positive impact on one's health-related quality of life (HRQoL). Specifically, these claims and representations suggest that Bimzelx can improve the negative effects of psoriasis (i.e., improve a patient's emotional and social functioning). However, we are unaware of support for the effect of Bimzelx on HRQoL in adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. We note that the clinical studies submitted to support the approval of Bimzelx assessed patient reported outcomes regarding psoriasis symptoms (i.e. itching, pain, and scaling), as measured by a Patient Symptom Diary, but HRQoL measures such as emotional or social functioning were not evaluated in those trials. Furthermore, the misleading impression of Bimzelx's effect on HRQoL is further exacerbated by the "transformative relief" portrayed in the TV ad. The portrayal of Bimzelx's efficacy is most evident, not with respect to a change in plaque psoriasis, but with a focus on the emotional and social improvements the patient undergoes throughout the TV ad. This is exemplified by the patient's melancholic appearance while alone at the beginning of the TV ad progressing to a cheerful, happy, socially active mood at the end. This misleading impression is especially concerning considering Bimzelx is associated with a Warning and Precaution regarding suicidal ideation and behavior. Therefore, the TV ad is misleading because it suggests that Bimzelx has been shown to demonstrate "transformative" improvements in a patient's emotional and social functioning when this has not been demonstrated. FDA is not aware of data to support these claims and presentations. If you have data to support these claims and presentations, please submit them to FDA for review.

We acknowledge that frames one through four of the TV ad includes the following, amidst other information, in the super, "Results may vary." However, this disclaimer does not correct or mitigate the misleading impression made by the TV ad that Bimzelx has been shown to demonstrate improvements in HRQoL.

The TV ad is misleading because the attention-grabbing visuals (e.g., man walks in front of a store with flashing lights while checking his reflection in the glass; he is greeted by friends with light jostling and touching his head; and, takes a selfie with friends during a screen-in-screen view), some with frequent scene changes, during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Bimzelx and makes the distribution of the drug in violation of the 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 Bimzelx that contain representations like those described above, and explaining your plan for the timely discontinuation of such communications, or for ceasing distribution of Bimzelx.

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 310 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 5309 under BLA 761151. 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 05:11:35 PM
On behalf of George Tidmarsh, M.D., Ph.D