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 279

Dear Kimberly Seay:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement "Can't Wait To Say 'I'm Back' 60" (US-BK-2400890) (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've always known how to fix things. … But with psoriatic arthritis, … My body felt broken. … Mornings were a nightmare. … But it's not going to control me anymore." (VO, frames 1-5)
- "With BIMZELX… I can't wait to say, … I'm Back." (VO, frames 6-8)
- "BIMZELX can deliver transformative relief of joint pain, and stiffness." (VO, frame 13)
- "*Bimzelx* (logo) CAN DELIVER **TRANSFORMATIVE RELIEF**" (on-screen text, frame 13)
- "I'm back to what moves me. … I'm back to reaching for new heights." (VO, frame 15-16)
- "I'm back to what inspires me." (VO, frame 20)
- "Give yourself a chance to say, 'I'm Back.'" (VO, frame 28)
- "**I'm Back**" (on-screen text, frames 8, 9, 11, and 28)

The totality of these claims and representations creates a misleading impression regarding the benefits of treatment with Bimzelx. First, the magnitude of change suggested by these claims implies a greater improvement than was demonstrated in the clinical trials for Bimzelx. Before Bimzelx treatment, the patients describe that their "body felt broken" and "mornings were a nightmare," but after treatment they were "back to reaching for new heights." According to the CLINICAL STUDIES section of the Prescribing Information (PI), the primary endpoint was the proportion of patients who achieved ACR50 response at Week 16, which represents a 50 percent improvement in disease activity. In Trial PsA-1 and Trial PsA-2,

ACR50 responses were achieved by 43.9% and 43.4% of patients treated with Bimzelx, respectively, compared to 10% and 6.8% of patients who received placebo, respectively.

Additionally, the totality of these claims and representations misleadingly suggests that Bimzelx has a positive impact on one's health-related quality of life (HRQoL) to a greater extent than has been demonstrated. Specifically, these claims and representations suggest that Bimzelx can provide "transformative relief" of the negative effects of psoriatic arthritis (i.e., transform a patient's emotional and social functioning). However, we are unaware of support for the effect of Bimzelx on HRQoL in adults with active psoriatic arthritis to the extent portrayed in the TV ad. We note that the clinical studies submitted to support the approval of Bimzelx assessed patient reported outcomes (PROs) using the Health Assessment Questionnaire- Disability Index (HAQ-DI)[1] and the Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT-Fatigue)[2]. (b) (4) [redacted] The extent of improvement in overall emotional or social functioning portrayed in the TV ad is not supported by these data. The portrayal of Bimzelx's efficacy is most evident, not with respect to a change in psoriatic arthritis, but focused on the emotional and social improvements each patient undergoes throughout the TV ad. 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 to a greater extent than has been demonstrated.

We acknowledge that frames 5-7, and 14-20 of the TV ad include the following, amidst other information, in the SUPER, "Results may vary." However, this disclaimer does not correct or mitigate the overall misleading impressions made by the TV ad.

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 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 Bimzelx that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Bimzelx.

[1] The HAQ-DI is a 20 item PRO instrument with scores ranging from 0 to 3. A lower HAQ-DI score indicates an improvement in function.
[2] The FACIT-Fatigue is a 13 item PRO instrument with scores ranging from 0 to 52 with 0 being the worst possible score.

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 279 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 5278 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 05:07:43 PM
On behalf of George Tidmarsh, M.D., Ph.D