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 337

Dear Kimberly Seay:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer broadcast advertisement "Chaquira" (US-BK-2400762) (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):

- "Life with hidradenitis suppurativa. It's a lot about bandages. …But they can't hide everything." (VO, frames 1-6)
- "Then I started Bimzelx. I'm starting to feel like… I'm back." (VO, frames 11-12)
- "Bimzelx can deliver transformative relief of HS symptoms." (VO, frame 15)
- "*Bimzelx (*logo*)* CAN DELIVER **TRANSFORMATIVE RELIEF** OF HS SYMPTOMS" (on-screen text, frame 15)
- "I'm back to making a difference." (VO, frame 19)
- "Give yourself a chance to say … I'm back." (VO, frames 28-29)
- "**I'm Back**" (on-screen text, frames 12, 19, and 29)

The proposed TV ad begins with scenes of the patient, by herself, applying bandages to her arm and subsequently wearing long sleeves and long pants in conjunction with the on-screen text in frames one and two, "MODERATE-TO-SEVERE **hidradenitis suppurativa**" (emphasis original). Then, after the introduction of Bimzelx on frame 11, the patient is shown unwrapping her bandages and getting "back" to exclusively wearing short sleeved or sleeveless shirts and dresses, exposing her previously covered underarm area, and enjoying various social interactions (e.g., dancing, stretching in yoga class, and hugging a friend) 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 hidradenitis suppurativa (HS) (i.e., improve a patient's emotional and social functioning). We note that the clinical studies submitted to support the approval of Bimzelx measured the Dermatology Life Quality Index (DLQI), but this instrument is not well-defined with adequate content validity in the target population of patients with moderate to severe HS to support claims and presentations regarding the impact of Bimzelx on health-related quality of life. 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 HS, 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 sitting alone with a tear rolling down her cheek 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 the super on frames four and five of the TV ad include the following, amidst other information, "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., patient amidst an industrious office scene and a busy restaurant engagement), 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 337 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 5336 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 05:11:11 PM
On behalf of George Tidmarsh, M.D., Ph.D