DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Milarca Kruse
Associate Director, U.S. Advertising & Promotion
Sanofi
450 Water Street
Cambridge, MA 02141

RE: BLA 761183
TZIELD® (teplizumab-mzwv) injection, for intravenous use
MA 377

Dear Milarca Kruse:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) television broadcast advertisement (TV ad), titled "Tzield 'WHEN' Anthem OLV/CTV: 60s Spot-Family History" (MAT-US-2410394 (v1.0)) for TZIELD® (teplizumab-mzwv) injection, for intravenous use (Tzield) submitted by Sanofi under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Tzield and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes claims and presentations that misrepresent the efficacy of Tzield. Specifically, the TV ad begins with a woman sitting on a stool on stage with a backdrop. She claims (emphasis original), "Everyone with type 1 diabetes has a moment of WH:EN" as four panels on the backdrop styled as a flipping clock start moving and spell out "WH:EN." She then claims, "WHEN I was diagnosed . . . . " along with the backdrop portraying an image of her talking to her doctor. The backdrop zooms back and starts flipping to display the words "WH:EN", as a young man takes the stage and claims, "WHEN I realized my life was about to change." The woman comes back on stage and the backdrop zooms out as she claims, "My biggest WH:EN? Discovering Tzield . . . . " The TV ad then continues with a mother and son duo who are baking a cake together. They come on stage as the backdrop is displaying the words "WH:EN" while claiming, "Our WHEN . . . . " At the end of the TV ad, the women, young man, and mother and son duo appear on stage as both the voiceover states and the backdrop flips to display, "SEIZE YOUR WH:EN."

The TV ad is misleading because it creates a misleading impression that treatment with Tzield can improve negative effects beyond those associated with type 1 diabetes (i.e., improve a patients emotional and social functioning) and enable a patient to go about their day without any perceived health related quality of life (HRQoL) problems "when" they "discover Tzield." This is further exacerbated by the misleading impression created by the apparent word play between "when" and "win", which implies that Tzield will enable patients to "win" the challenge of type 1 diabetes when this has not been demonstrated. According to the "**What is TZIELD?**" section of the Medication Guide (in pertinent part, underlined

emphasis added): “TZIELD is a prescription medicine used to delay the onset of Stage 3 type 1 diabetes . . . . ” FDA is not aware of data to support the implication that taking Tzield will have a positive impact on one’s HRQoL and will allow patients to “win” or overcome their type 1 diabetes. Therefore, claims and presentations suggesting a positive impact on one’s HRQoL or allowing patients to “win” or overcome their type 1 diabetes are misleading. If you have data to support these claims and presentations, please submit them to the FDA for review.

In addition, the TV ad is misleading because of the frequent scene changes and compelling, attention-grabbing visuals (e.g., the dog skating on a skateboard) during the presentation of the major statement, which interfere with the comprehension of the major statement.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Tzield 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 Sanofi 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 Tzield that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Tzield.

If you believe that your product is 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 377 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 6374 under BLA 761183.

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 05:17:43 PM
On behalf of George Tidmarsh, M.D., Ph.D