DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Donna Boyce, M.S.
Head, Global Regulatory Sciences
Pfizer, Inc.
66 Hudson Boulevard East
New York, NY 10001

RE: NDA 216956
VELSIPITY™ (etrasimod) tablets, for oral use
MA 228

Dear Donna Boyce:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (PP-V1A-USA-1028) (TV ad) for VELSIPITY™ (etrasimod) tablets, for oral use (Velsipity) submitted by Pfizer, Inc. (Pfizer) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Velsipity and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The images of a creature depicting ulcerative colitis (UC) throughout the TV ad misleadingly overstate the efficacy of Velsipity. The creature turns red and is out of control when the main character talks about his symptoms before starting Velsipity. The main character is very bothered by the creature's disruptive actions. Then the creature turns blue and is calmer despite what is happening around him. The main character is now not bothered at all by the creature's disruptive actions. According to the CLINICAL STUDIES section of the FDA-approved full Prescribing Information (PI), the efficacy of Velsipity was evaluated by assessing the proportion of subjects achieving clinical remission at Week 12 and Week 52 in Study UC-1 and at Week 12 in Study UC-2. In Study UC-1, clinical remission was achieved in 27% and 32% of the patients at Week 12 and Week 52, respectfully, and 26% of the patients at Week 12 in Study UC-2. The magnitude of change depicted in the visuals implies a greater improvement in clinical remission than had been demonstrated.

The TV ad is misleading because the images of the creature shaking the main character's leg trying to get his attention, rolling around on the ground, and chewing on something it found outside 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 Velsipity 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 Pfizer 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 Velsipity that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Velsipity.

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 undersigned at 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 228 in addition to the NDA 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 300 under NDA 216956. Questions related to the submission of your response letter should be emailed to the OPDP RPM at 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 05:13:07 PM
On behalf of George Tidmarsh, M.D., Ph.D