DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Nikkolette Hill
Head, RA US Advertising and Promotion
AbbVie, Inc.
1 N. Waukegan Road, Dept PA95, Bldg ABV1
North Chicago, IL 60064

RE: NDA 202811
LINZESS® (linaclotide) capsules, for oral use
MA 1615

Dear Nikkolette Hill:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (US-LIN-240235) (TV ad) for LINZESS® (linaclotide) capsules, for oral use (Linzess) submitted by AbbVie, Inc. (AbbVie) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Linzess and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The major statement is presented from Frames 10 through 16, during which the TV ad depicts the main character bringing home a surprise gift for his daughter. They are shown laughing while she tries to get the present from him and he playfully pulls it away. Then the daughter is shown spying on her parents while dancing, while everyone is smiling and upbeat. Finally, the daughter is given the present and she excitedly opens it to reveal dancing shoes. She quickly runs over to her dad with a big smile. The TV ad is misleading because the frequent scene changes and compelling and attention-grabbing visuals during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

For the reason described above, the TV ad misbrands Linzess 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 AbbVie 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 Linzess that contain representations like

those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Linzess.

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 1615 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 3543 under NDA 202811. 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 05:13:23 PM
On behalf of George Tidmarsh, M.D., Ph.D