DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Angela Muñoz
Director, Regulatory Affairs - Advertising and Promotion
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536

RE: NDA 218316
WEGOVY® (semaglutide) tablets, for oral use
MA 6

Dear Angela Muñoz:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television broadcast advertisement "January 2026 Pill Spot" (US25SEMO01839) (TV ad) for WEGOVY® (semaglutide) tablets, for oral use (Wegovy) submitted by Novo Nordisk Inc. (Novo Nordisk) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Wegovy 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 (in pertinent part, emphasis original):

- **Voiceover (VO)**: "Meet Wegovy pill."
  ON-SCREEN TEXT: "**Meet Wegovy® pill**"

- **VO**: "The first and only FDA approved GLP-1 weight loss pill."
  ON-SCREEN TEXT: "**Only GLP-1 weight-loss pill**"

- **VO**: "Weight loss has never looked like this."

- **VO**: "Now you can live lighter by losing weight."
  ON-SCREEN TEXT: "**LIVE LIGHTER™ by losing weight**"

- **VO**: "The power of Wegovy, now in the palm of your hand."

- **VO**: "Weight loss with Wegovy isn't a shortcut. It's a way forward."

- **VO**: "Live lighter by losing weight and keeping it off."
  ON-SCREEN TEXT: "**LIVE LIGHTER™ by losing weight and keeping it off**"

The totality of these claims and presentations misleadingly suggest that because of its dosage form (i.e., pill), Wegovy offers an advancement or improvement (i.e., superior efficacy and/or safety) over other currently approved glucagon-like peptide-1 (GLP-1) treatments for weight loss. Specifically, these claims and presentations misleadingly imply that Wegovy in pill form uniquely enables patients to achieve outcomes that were not previously possible with other GLP-1 treatments for weight loss. For example, the claims “live lighter” and “a way forward” misleadingly imply additional weight loss compared to other currently approved GLP-1 treatments, when this has not been demonstrated. Additionally, they misleadingly imply benefits beyond physical weight loss such as emotional relief, reduced psychological burden, hope, or direction for patients’ lives, positioning the drug as a solution to broader life challenges rather than a treatment for a specific condition, when this has also not been demonstrated.

According to the FDA-approved Wegovy Prescribing Information (PI), the CLINICAL STUDIES section states (in pertinent part), “The efficacy of WEGOVY 25 mg oral once daily tablet was . . . evaluated in a . . . placebo-controlled trial.” FDA is not aware of data to support the implication that Wegovy, in pill form, is superior to other currently approved GLP-1 treatments for weight loss in terms of efficacy and/or safety. Therefore, claims and presentations suggesting such are misleading. If you have data to support these claims and presentations, please submit them to the FDA for review.

In addition, the major statement includes presentations where there is information in the SUPERs that is not from the corresponding audio. Therefore, the TV ad is misleading because it fails to present the major statement concurrently using both audio and text (dual modality).

Conclusion and Requested Action

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

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 6 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 37 under NDA 218316. 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}

Ankur Kalola, PharmD, RAC
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

{See appended electronic signature page}

Sapna Shah, PharmD
Team Leader
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

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/

ANKUR S KALOLA
02/05/2026 12:04:39 PM

SAPNA SHAH
02/05/2026 12:05:57 PM