DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Colleen Donovan, Director
Regulatory Advertising & Promotion
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936

RE: BLA 125326
Kesimpta® (ofatumumab) infection, for subcutaneous use
MA 1749

Dear Colleen Donovan:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) television advertisement (TV ad), titled "KSM DTC My Time My Way :60 TVC Campaign Expansion 11-24" (FA-11225957) for Kesimpta® (ofatumumab) infection, for subcutaneous use (Kesimpta) submitted by Novartis Pharmaceuticals Corporation (Novartis) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Kesimpta and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Frame seven of the TV ad includes the following claim and presentation (emphasis original):

- Voiceover "When ready, I take it at home in one minute a month."
- SUPER: "Treatment TIME Take it at home **1 MINUTE A MONTH**."

This claim and presentation are misleading because they suggest that the overall administration process of Kesimpta can be completed in "1 minute," thereby oversimplifying the steps involved. The FDA-approved Instructions for Use for Kesimpta include a number of detailed steps required for proper administration of the product which take longer than "1 minute" to complete. Furthermore, according to the DOSAGE AND ADMINISTRATION section of the FDA-approved Prescribing Information for Kesimpta (in pertinent part), "The first injection of KESIMPTA should be performed under the guidance of a healthcare professional." We acknowledge that a small SUPER appears at the bottom of the screen stating, "…Typical administration time when ready to inject," however, this does not mitigate the misleading impression.

The TV ad is misleading because the attention-grabbing visuals (e.g., the zooming effect under the woman doing yoga and toward the yoga teacher, the zooming effect through the train tunnel and toward the father and child, the zooming effect with the microphone moving toward Jamie Lynn Sigler, and Jamie Lynn Sigler scoring the winning shot while playing air hockey with her family) during the presentation of the major statement interferes with comprehension of the major statement.

Conclusion and Requested Action

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

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 1749 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 8418 under BLA 125326. 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 05:14:27 PM
On behalf of George Tidmarsh, M.D., Ph.D