DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Peter Isikwe
Director, Regulatory Affairs, Advertising/Promotion – US & Canada
BeOne Medicines USA, Inc.
311 Pennington-Rocky Hill Rd, Bldg 51-Ste 1358
Pennington, NJ 08534

RE: BLA 761232
TEVIMBRA® (tislelizumab-jsgr) injection, for intravenous use
MA 47

Dear Peter Isikwe:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, two Teams Backgrounds, "TEVIMBRA Pan Tumor Teams Backgrounds" (1124-TEV-PRC-039) (branded backgrounds) for TEVIMBRA® (tislelizumab-jsgr) injection, for intravenous use (Tevimbra) submitted by BeOne Medicines USA, Inc. (BeOne) under cover of Form FDA 2253. FDA has determined that the branded backgrounds are false or misleading. Thus, the branded backgrounds misbrand Tevimbra and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The branded backgrounds contain claims and representations about the use and/or benefits of Tevimbra. For example, "Option 1" includes the claim, "**BRINGING MORE** TO THE TABLE IN UPPER GI CANCERS" (emphasis original), in direct conjunction with a visual of a long, curving dinner table similar to the upper digestive tract. "Option 2" includes the claim, "**APPROVED** IN CERTAIN UPPER GI CANCERS" (emphasis original). Because the branded backgrounds contain representations or suggestions relating to an indication for use of a particular drug product (Tevimbra), they are required to include risk information as well. However, the branded backgrounds fail to communicate **any** risk information about the product. By omitting the major side effects associated with Tevimbra, the branded backgrounds fail to provide material information about the consequences that may result from the use of the drug and create a misleading impression about the drug's safety.

The branded backgrounds are misleading because they fail to provide material information regarding Tevimbra's full FDA-approved indication. Specifically, the INDICATIONS AND USAGE section of the FDA-approved Prescribing Information (PI) states (in pertinent part):

- "TEVIMBRA, in combination with platinum-containing chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1)."

- "TEVIMBRA, as a single agent, is indicated for the treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor."
- "TEVIMBRA, in combination with platinum and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥1)."

The branded backgrounds suggest the use of Tevimbra for the treatment of "upper GI cancers," but they do not specify that Tevimbra is indicated as noted above. By failing to adequately communicate the indication for Tevimbra, the branded backgrounds create a misleading impression about the drug's FDA-approved indication.

Conclusion and Requested Action

For the reasons described above, the branded backgrounds misbrand Tevimbra 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 BeOne 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 Tevimbra that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Tevimbra.

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 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 47 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 5039 under BLA 761232.

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}

Rebecca Falter, PharmD, BCACP
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Emily Dvorsky, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
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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/

REBECCA A FALTER
12/17/2025 03:52:08 PM

EMILY M DVORSKY
12/17/2025 04:25:30 PM