DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Nicole Van De Vaarst
Senior Manager, U.S. Commercial Regulatory Affairs
Bristol-Myers Squibb
3401 Princeton Pike
Lawrenceville, NJ 08648

RE: BLA 761381
OPDIVO QVANTIG™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
MA 116

Dear Nicole Van De Vaarst:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to consumer (DTC) broadcast advertisement (1992-US-2500295) (TV ad) for OPDIVO QVANTIG™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use (Opdivo Qvantig), submitted by Bristol-Myers Squibb (BMS) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Opdivo Qvantig 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 representations (in pertinent part):

- "Cancer isn't me, it's something I treat. And the less time I spend treating cancer, the better. This is me." (Hero, 0:00)
- "… Opdivo Qvantig lets you receive treatment quickly – in as little as 3 minutes" (Voice Over, 0:15)
- "INJECTION IN AS LITTLE AS 3 MINUTES" (SUPER, 0:18)
- "A treatment that's faster." (Voice Over, 1:08)
- A TREATMENT THAT'S FASTER (SUPER, 1:08)

These claims are accompanied by various scenes throughout the TV ad depicting three "heroes" seemingly receiving treatment in a clinical setting but as the screen zooms out, are actually in various social settings (e.g., in a café with friends, at a movie theater with family, sitting and gaming at an arcade, and receiving a spa treatment). The totality of these representations makes the TV ad misleading by suggesting that patients receiving Opdivo Qvantig will spend little to no time in a clinical setting, but instead, will spend their time engaging in activities that they enjoy (i.e., "This is me"). However, this may not be the case for every patient during every treatment session. This impression is furthered by the change in lighting for each "hero" from dark to bright and each "hero's" mood transitioning from

serious to happy. We acknowledge the LOWER-THIRD SUPER presented in the TV ad which states "…This does not account for all aspects of treatment time. Actual clinic time may vary;" however, this does not correct or mitigate the misleading impression created by the suggestions or representations.

The TV ad is misleading because the attention-grabbing visuals and frequent scene changes (i.e., one "hero" playing arcade games, a second "hero" having coffee with friends then at a spa, a third "hero" at a movie theater) during the presentation of the major statement interfere with the comprehension of the major statement.

Conclusion and Requested Action

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

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 **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 116 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 5115 under BLA 761381.

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 05:15:05 PM
On behalf of George Tidmarsh, M.D., Ph.D