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: NDA 214998
CAMZYOS® (mavacamten) capsules for oral use
MA 432

Dear Nicole Van de Vaarst:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) television advertisement (TV ad), titled "TV 0:60 STORYBOARD: FEEL/SEE BASKETBALL" (3500-US-2500152) for CAMZYOS® (mavacamten) capsules for oral use (Camzyos) submitted by Bristol Myers Squibb (BMS) under cover of Form FDA 2253.[1] FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Camzyos 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):

- **VO**: "Back to the game I love." (Frame 1)
- **VO**: "It's great to be able to keep up with the guys again." (Frame 2)
- **VO**: "With CAMZYOS my symptoms have improved and I can be more active now." (Frame 5)
- **VO**: "It's a difference I can feel…" (Frame 6)
- **VO**: "… and they can see." (Frame 7)
- **VO**: "And she can too." (Frame 8)
- **VO**: "It's great to be playing again." (Frame 19)

These claims are accompanied by various presentations throughout the TV ad. Specifically, the TV ad begins with a "male hero greeting his 3 friends at a local basketball court in a suburban park." They start playing a "light game of two on two." The men continue to play their game, and the male hero can be seen running, shooting a basket, and going to high-five his friend. After the game, the male hero's daughter runs to give him a hug and he is seen being lightly tackled to the floor. The male hero and his daughter are then playing basketball. The male hero appears tired and takes a break and is seen "greeting" his friends and then sitting with his family. The male hero's daughter then pulls him up towards the

[1] The Form FDA 2253 submission included the final produced TV ad as well as a storyboard annotated with frame numbers. We have referred to those frame numbers in this letter to facilitate communication of our concerns.

basketball court and wants him to teach her how to play basketball. The male hero is seen teaching her how to play basketball and how to shoot the ball. He is then seen picking her up overhead as she shoots the ball into the basket.

The totality of these claims and presentations create a misleading impression that *all* patients with obstructive hypertrophic cardiomyopathy (HCM), while being on treatment with Camzyos, can expect to engage in these activities (e.g., playing basketball, being lightly tackled to the ground, lifting a child overhead) and remain functional with little to no diminishment of or restrictions to daily activities, when this has not been demonstrated. According to the CLINICAL STUDIES, EXPLORER-HCM section of the FDA-approved prescribing information (PI) for Camzyos (in pertinent part), "A greater proportion of patients met the primary endpoint at Week 30 in the CAMZYOS group compared to the placebo group (37% vs. 17%, respectively, p=0.0005) . . . . " While treatment with Camzyos may help patients with HCM improve their functional capacity and symptoms, these data do not support implications that all patients can reasonably expect to perform the level of activity depicted in the TV ad or remain functional with little to no diminishment of or restrictions to daily activities while being on treatment with Camzyos.

We acknowledge the disclaimer "Individual results may vary." However, the inclusion of this statement does not mitigate the misleading impression created by the TV ad. Therefore, claims and presentations implying that all patients can reasonably expect to perform this level of activity or functioning while being on treatment with Camzyos are misleading.

Moreover, the TV ad creates a misleading impression regarding the mechanism of action of Camzyos. Specifically, the TV ad states, "CAMZYOS works by targeting what's causing oHCM" (VO, Frame 9). The phrase, "targeting what's causing" is vague and misleadingly suggests that Camzyos works by correcting the underlying genetic defects that lead to HCM. According to the CLINICAL PHARMACOLOGY section of the PI, "Mavacamten is an allosteric and reversible inhibitor selective for cardiac myosin" (in pertinent part, emphasis added). Therefore, the claim that "Camzyos works by targeting what's causing oHCM" is misleading.

The TV ad is also misleading because it includes claims and presentations about the uses and benefits of Camzyos but omits material risk information pertaining to the warning and precaution for embryo-fetal toxicity. Specifically, the major statement does not communicate the following from the **"Before taking CAMZYOS, tell your healthcare provider about all of your medical conditions, including if you:"** section of the Medication Guide (in pertinent part; underlined emphasis added), "Are pregnant or plan to become pregnant. CAMZYOS may harm your unborn baby . . . . " By omitting this material risk information, the TV ad minimizes the warning and precaution for embryo-fetal toxicity and creates a misleading impression of the drug's safety.

In addition, the TV ad is misleading because the size and style of font, contrast with background, and placement on screen of the text portion of the major statement, do not allow the information to be read easily. Furthermore, the TV ad is misleading because of the frequent scene changes and compelling, attention-grabbing visuals (e.g., the male hero's friends stretching and moving, the male hero greeting his friends in the park, the male hero's wife and daughter petting a dog, the male hero playing basketball with his daughter) during

the presentation of the major statement, which interfere with the comprehension of the major statement.

Conclusion and Requested Action

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

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 432 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 5431 under NDA 214998. 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 05:17:22 PM
On behalf of George Tidmarsh, M.D., Ph.D