DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Traci Dickson
Senior Manager Regulatory Affairs, Advertising and Promotion
BeOne Medicines USA, Inc.
311 Pennington-Rocky Hill Rd, Bldg 51-Ste 1358
Pennington, NJ 08534

RE: NDA 218785
BRUKINSA® (zanubrutinib) capsules, for oral use
BRUKINSA® (zanubrutinib) tablets, for oral use
MA 31

Dear Traci Dickson:

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 (DTC) broadcast advertisement (0525-BRU-PRC-137) (TV ad) for BRUKINSA® (zanubrutinib) capsules and tablets, for oral use (Brukinsa) submitted by BeOne Medicines USA, Inc. (BeOne) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Brukinsa and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad begins with an older man looking confused with multiple images of questions presented regarding best treatment options, duration of results, and potential next steps. The voiceover states, “With a CLL diagnosis, there may be moments that seem unclear. But when it’s time for treatment, one thing is clear: Brukinsa.” The next scenes depict the man in a serene environment ascending a mountain via gondola. The man is then seen in the gondola with a hopeful grin as benefit claims are both audibly and visually presented. The final scenes of the TV ad present the man smiling and overlooking a vast landscape in the high mountaintop with his family with the voiceover, “See your future clearly again with Brukinsa. Ask your doctor about Brukinsa, the CLL treatment that keeps you in control.”

The totality of these claims and presentations creates a misleading impression regarding the risk profile of Brukinsa. Specifically, the TV ad implies that when it’s time for treatment with Brukinsa, patients are able to travel long distances or for prolonged periods since they are “in control” of their CLL treatment. However, adverse reactions are most likely to happen when patients start using the drug or when the dosage changes. Patients on Brukinsa are required to be seen by their health care provider on a regular basis to assess the drug’s efficacy and potential adverse effects. Therefore, these claims and presentations create a misleading impression that patients on Brukinsa can maintain a normal, active lifestyle, thereby downplaying the serious side effects and monitoring requirements.

In addition, the major statement includes presentations where the verbatim complete transcript or verbatim key terms or phrases from the corresponding audio do not appear in dual modality, along with 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).

Furthermore, the major statement is presented when the TV ad's emotional story arc reaches its peak. Specifically, the man finally reaches the top of the mountain and exits the gondola while holding hands with his wife. When he meets the rest of his family on top of the mountain, they are seen laughing, embracing in hugs, and engaging in complex handshakes and fist bumps. Afterwards, the scenes depict the man displaying a camera and reviewing a map before embracing his wife and heading outdoors to overlook the mountaintop with the entire family and getting a picture taken with his wife. Therefore, the TV ad is misleading because these compelling and attention-grabbing visuals during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

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

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 31 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 5027 under NDA 218785. 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}

Valerie Guerrier, PharmD
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

{See appended electronic signature page}

Jina Kwak, PharmD, RAC
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/

VALERIE GUERRIER
01/07/2026 02:55:50 PM

JINA KWAK
01/07/2026 02:57:39 PM