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 38

Dear Traci Dickson:

The Food and Drug Administration has completed evaluation of your response to our Untitled Letter dated May 12, 2026. Based on our evaluation, it appears that you have addressed the violations contained in this Untitled Letter.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during subsequent surveillance or through other means.

If you have any questions or comments, 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 38 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 5038 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

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
06/16/2026 08:30:42 AM