DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Rowell Medina
Director, Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington, DE 19803-8355

RE: NDA 216387
CALQUENCE® (acalabrutinib) capsules, for oral use
MA 824

Dear Rowell Medina:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a DTC broadcast advertisement (TV ad), titled "2025 CALQUENCE DTC Commercial - Major Statement Update" (US-99628) for CALQUENCE® (acalabrutinib) capsules, for oral use (Calquence) submitted by AstraZeneca Pharmaceuticals LP (AstraZeneca) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Calquence 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 presentation (emphasis original):

- Frames 1- 2 VO: "When you're ready to begin treatment… for chronic lymphocytic leukemia, CALQUENCE helps you do the fighting."
- Frame 3 VO: "And you can do the exploring."
- Frame 3 Graphic: "**exploring**"
- Frame 5 VO: "You can do the splashing…"
- Frame 5 Graphic: "**splashing**"
- Frame 6 VO: "…the sightseeing…"
- Frame 6 Graphic: "**sightseeing**"
- Frame 7 VO: "…and the playing."
- Frame 7 Graphic: "**playing**"

These claims are presented in conjunction with images of a man on top of a cliff exploring, a woman in a pool splashing with her grandson, a couple at an overlook sightseeing and a man playing with a dog. This presentation creates a misleading impression regarding the risk profile of Calquence. Specifically, adverse reactions are most likely to happen when patients first begin using the drug, when they discontinue it, or when the dosage changes. Patients on Calquence 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, this presentation creates a

misleading impression that patients on Calquence can maintain a normal, active lifestyle while undergoing treatment, thereby downplaying the serious side effects and monitoring requirements.

The TV ad is misleading because the distracting visuals such as a man playing with a dog, a woman splashing in the swimming pool, and multiple background scene changes while a couple goes sightseeing 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 Calquence 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 AstraZeneca 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 Calquence that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Calquence.

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 **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 824 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 908 under NDA 216387.

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 05:07:04 PM
On behalf of George Tidmarsh, M.D., Ph.D