DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Sharon Watson, PharmD, MS Pharm, MBA
Director, Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals LP
200 Orchard Ridge Drive
Gaithersburg, MD 20878

RE: NDA 218197
TRUQAP® (capivasertib) tablets, for oral use
MA 169

Dear Sharon Watson:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication(s), DTC broadcast advertisement "2025 TRUQAP Branded Patient TV Spot" (TV ad) for TRUQAP® (capivasertib) tablets, for oral use (Truqap) 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 Truqap and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The major statement is presented from 0:32-1:13, during which the TV ad depicts a woman approaching an outdoor concert, walking through a park, and approaching and attending a party at the end of a pier, all while objects "unfold" from the page and pages turn. The TV ad is misleading because the frequent scene changes, some with 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 Truqap 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 Truqap that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Truqap.

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 169 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 251 under NDA 218197. 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 05:15:42 PM
On behalf of George Tidmarsh, M.D., Ph.D