DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Payal Patel
Director, Regulatory Advertising & Promotion Policy
GlaxoSmithKline LLC
410 Blackwell Street
Durham, NC 27701

RE: NDA 215499
APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use
MA 706

Dear Payal Patel:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer broadcast advertisement (TV ad), titled “A Game 60 TV Ad Pool Out 2025” (PM-US-CBT-STBD-250001) for APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use (Apretude) submitted by GlaxoSmithKline (on behalf of ViiV Healthcare) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Apretude 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 scenes of individuals engaging in various activities including two men on a date, a man bowling, and a woman retouching her lips in a mirror as she arrives at a house party. Throughout these scenes, a glowing “A” graphic illuminates over these individuals. These scenes are accompanied by the voiceover claims “Playdate? You bring your A-game;” “Ready to score? You bring your A-game;” and “Bring your A-game to your sexual wellness.” After Apretude is introduced, the TV ad progresses with the individuals engaging in sexually suggestive behaviors for the remainder of the TV ad. For example, the woman makes eye contact with a man and uses suggestive glances conveying sexual interest. In another scene, the man bowling starts interacting with another man who was checking him out with sexual interest. The TV ad ends with the claims “You bring your A-game to everything you do. Ask your doctor about APRETUDE.” with accompanying visuals of couples walking together and the letter “A” glowing over them. These claims and presentations misleadingly suggest that Apretude provides a sense of sexual freedom without the need to practice safer sex to reduce the risk of sexually transmitted infections (STIs). This misleading impression is further exacerbated by claims such as, “Playdate?” and “Ready to score?” and scenes with the individuals engaging in sexually suggestive behaviors as described above. According to the WARNINGS AND PRECAUTIONS section of the FDA-approved product labeling (PI), Apretude is used as “part of a comprehensive prevention strategy including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs).” In addition,

this section of the PI notes that individuals should be counseled on the use of other prevention methods and supported in their effort to reduce sexual risk behavior. The FDA acknowledges that the TV ad includes the statement "APRETUDE does not prevent other sexually transmitted infections. Practice safer sex to reduce your risk." However, these statements do not mitigate the overall misleading impression.

Furthermore, the TV ad is misleading because the frequent scene changes and attention-grabbing visuals (e.g., the sexually suggestive behaviors described above) 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 Apretude 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 GlaxoSmithKline 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 Apretude that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Apretude.

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 706 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 0800 under NDA 215499. 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 05:15:27 PM
On behalf of George Tidmarsh, M.D., Ph.D