DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Nicole Lare
Director, Regulatory Affairs
Bayer HealthCare Pharmaceuticals, Inc.
100 Bayer Boulevard, P.O. Box 915
Whippany, NJ 07981

RE: NDA 212099
NUBEQA® (darolutamide) tablets, for oral use
MA 997, 1034

Dear Nicole Lare:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communications, a direct-to-consumer (DTC) YouTube video (PP-NUB-US-4393-1)[1] (video) and a Spanish language broadcast advertisement (PP-NUB-US-4601-1)[2] (TV ad) for NUBEQA® (darolutamide) tablets, for oral use (Nubeqa) submitted by Bayer HealthCare Pharmaceuticals, Inc. (Bayer) under cover of Form FDA 2253. FDA has determined that the video and TV ad are false or misleading. Thus, the video and TV ad misbrand Nubeqa and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The video and TV ad are misleading because they include claims and representations about the benefits of Nubeqa but omit important risk information associated with the drug. The video and TV ad include the following claim:

- AVO (0:29): "Nubeqa may cause serious side effects including heart disease and seizure."

However, the video and TV ad fail to communicate material information from the FDA-approved Patient Information (PPI). Specifically, the "**What are the possible side effects of NUBEQA?**" section of the PPI states the following (in pertinent part, bold emphasis original, underline emphasis added):

- "**Heart disease.** Blockage of the arteries in the heart (ischemic heart disease) that <u>can lead to death</u> has happened in some people during treatment with NUBEQA."
- "**Seizure.**…<u>You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others.</u>"

[1] The video is available at https://www.youtube.com/watch?v=5hOyJzMiwZk (last accessed April 28, 2026).
[2] The TV ad is the Spanish translation of the video and was submitted to OPDP with a Certificate of Translation.

By omitting this important risk information, the video and TV ad fail to provide material information about the consequences that may result from the use of Nubeqa and create a misleading impression about the drug's safety.

In addition, the major statements include presentations where the verbatim complete transcript or verbatim key terms or phrases from the corresponding audio do not appear in dual modality. Therefore, the video and TV ad are misleading because they fail to present the major statement concurrently using both audio and text (dual modality).

Furthermore, the video and TV ad are misleading because the attention-grabbing visuals (e.g., vibrant colors, constant motion within the scenes, frame transitions and camera movements) and frequent scene changes during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

For the reasons described above, the video and TV ad misbrand Nubeqa and make 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 Bayer 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 Nubeqa that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Nubeqa.

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 997 and MA 1034 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 5997 and 6034 under NDA 212099. 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}

Jeena Sun, PharmD, MBA
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Emily Dvorsky, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
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/

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04/28/2026 02:49:33 PM

EMILY M DVORSKY
04/28/2026 02:53:03 PM