DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Tracey M. Henderson, MS, MBA
Promotional Regulatory Affairs Review Director, CVRM
AstraZeneca
1800 Concord Pike
Wilmington, DE 19803

RE: NDA 202293
FARXIGA® (dapagliflozin) tablets, for oral use
MA 2327

Dear Tracey Henderson:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) television broadcast advertisement "FARXIGA DTC TV: 45 – Places You Want to Be v2" (US-96960) (TV ad) for FARXIGA® (dapagliflozin) tablets, for oral use (Farxiga) submitted by AstraZeneca under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Farxiga 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 the following claims and representations about benefits and use of Farxiga (emphasis original):

- **Voice Over (VO):** "If you have heart failure or chronic kidney disease, Farxiga can help you keep living life because there are places, you'd like to be."
- **First Superimposed text (SUPER):** "FARXIGA can help you keep living life by reducing the risk of cardiovascular death"
- **Graphic:** "farxiga (dapagliflozin) 10 mg tablets"
- **Second SUPER:** "For adults with chronic kidney disease or heart failure, when the heart cannot pump enough blood to the rest of the body."
- **Third SUPER:** "Not for people with polycystic kidney disease, or those recently or currently taking immunosuppressive therapy for kidney disease."

The TV ad is misleading because it misleadingly represents that Farxiga was approved only on the single endpoint of "reducing the risk of cardiovascular death" in adults with chronic kidney disease (CKD) or heart failure (HF) when this is not the case. The approval of Farxiga in patients with CKD was based on the reduction in the incidence of the primary *composite* endpoint of ≥50% sustained estimated glomerular filtration rate (eGFR) decline,

progression to end-stage kidney disease (ESKD), cardiovascular (CV) or renal death. Similarly, the approval of Farxiga in patients with HF was based on two trials that evaluated on the reduction of the incidence of the primary *composite* endpoint of CV death, hospitalization for HF or urgent HF visit.

According to the INDICATIONS AND USAGE section of the FDA-approved Prescribing Information (PI), the FDA-approved indications for CKD and HF are the following (emphasis added):

> FARXIGA (dapagliflozin) is indicated:
>
> - To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
>
> - To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure.

By failing to adequately communicate all of the components that contribute to the indications for these respective populations, the TV ad creates a misleading impression about the FDA-approved indications for Farxiga in adults with CKD and HF.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Farxiga 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 Farxiga that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Farxiga.

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 2327 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 1654 under NDA 202293. 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}

Adesola Adejuwon, PharmD, MBA
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Sapna Shah, PharmD
Team Leader
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/

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SAPNA SHAH
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