DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Tara Ruszczyk, PharmD
Director, Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

RE: NDA 204629
JARDIANCE® (empagliflozin tablets), for oral use
MA 4235

Dear Tara Ruszczyk:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (TV ad) entitled "jardiancetdtvspot6movienight-cm" (PC-US-137344) for JARDIANCE® (empagliflozin tablets), for oral use (Jardiance) submitted by Boehringer Ingelheim Pharmaceuticals, Inc. (BI) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Jardiance and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad communicates information pertaining to the indications and limitations of use for Jardiance through audio, SUPERs, and visuals. At the same time, the TV ad presents fast-paced visuals that feature choreographed dancing to the background music throughout multiple scene changes. Specifically, a man is seen singing a jingle and then dancing along with other individuals at a "movie night" event at the park. He continues to sing and dance as additional movie-related visuals (e.g., enlarged popcorn bucket props, a ticket booth, a movie screen, lawn blankets accenting choreographed dance movements, flashing cameras) appear on screen. The presentation of these compelling and attention-grabbing visuals, which are unrelated to the indications and limitations of use presented in the audio, on-screen SUPERs and visuals, in addition to the frequent scene changes and other competing modalities such as the background music, compete for the consumer's attention. As a result, the presentation of the indications and limitations of use is undermined by multiple, competing presentational aspects that distract the viewer from important information about the benefits of Jardiance and, therefore, creates a misleading impression about the drug's efficacy.

In addition, the TV ad is misleading because the size and style of font, contrast with background, and placement on screen of the text portion of the major statement, do not allow the information to be read easily. Furthermore, the TV ad is misleading because of the frequent scene changes and compelling, attention-grabbing visuals (e.g., a photo stand-in with face holes, a movie screen, a man throwing up popcorn and catching in mouth, enlarged popcorn bucket props, a man operating a film projector with flashing lights, a dog wearing 3D

glasses) during the presentation of the major statement, which interfere with the comprehension of the major statement.

Conclusion and Requested Action

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

If you believe that your product is 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 4235 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 2543 under NDA 204629. 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 05:16:47 PM
On behalf of George Tidmarsh, M.D., Ph.D