DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Patricia Thomas, Senior Director
Global Regulatory Affairs, Advertising & Promotion
Takeda Pharmaceuticals USA, Inc.
40 Landsdowne Street
Cambridge, MA 02139

RE: NDA 217564
FRUZAQLA® (fruquintinib) capsules, for oral use
MA 174

Dear Patricia Thomas:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (US-FRZ-0501v1.0)[1] (TV ad) for FRUZAQLA® (fruquintinib) capsules, for oral use (Fruzaqla) submitted by Takeda Pharmaceuticals USA, Inc. (Takeda) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Fruzaqla and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad is misleading because it presents efficacy claims and representations for Fruzaqla but fails to communicate the warning and precaution of gastrointestinal perforation. By omitting this risk associated with Fruzaqla, the TV ad fails to provide material information about the consequences that may result from the use of Fruzaqla and creates a misleading impression about the drug's safety.

The TV ad is misleading because the attention-grabbing visuals (e.g., a zooming effect toward and through a vase of flowers transitioning to a man playing fetch with a dog) during the presentation of the major statement interferes with comprehension of the major statement.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Fruzaqla and makes 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 Takeda 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

[1] The material ID referenced on the DTC broadcast advertisement does not include "v1.0."

the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Fruzaqla that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Fruzaqla.

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 174 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 5123 under NDA 217564. 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 05:16:35 PM
On behalf of George Tidmarsh, M.D., Ph.D