DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Nikki Hill, PharmD
Head of Regulatory Affairs, U.S. Advertising and Promotion
AbbVie, Inc.
1 N. Waukegan Road, Dept. PA95, Bldg. ABV1
North Chicago, IL 60064

RE: NDA 215206
Qulipta® (atogepant) tablets, for oral use
MA 903

Dear Dr. Hill:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television advertisement (TV ad), (US-QLP-250169) for Qulipta® (atogepant) tablets, for oral use (Qulipta) submitted by AbbVie, Inc. under cover of Form 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Qulipta and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Frame two of the TV ad features a woman in a dark bedroom, appearing to experience migraine pain, in conjunction with the voiceover, “Before preventing migraine with QULIPTA, it was hard keeping plans.” Frames one and three through seven of the TV ad show the same woman, smiling and actively engaged in chaperoning her child’s field trip, seemingly without migraine symptoms, in conjunction with on-screen text stating, “QULIPTA MORE ZERO-MIGRAINE DAYS POSSIBLE.” Frame nine of the TV ad shows the same woman smiling in her kitchen in conjunction with the voiceover and SUPER, “QULIPTA-the forget-you-get migraine medicine.” These claims and compelling before-and-after presentation misleadingly create an impression of total migraine prevention when this has not been demonstrated. According to the CLINICAL STUDIES section of the FDA-approved Prescribing Information for Qulipta, the primary efficacy endpoint was the change from baseline in mean monthly migraine days (MMD) across the 12-week treatment period. Study 1 and Study 2 included patients with episodic migraine and Study 3 included patients with chronic migraine. In patients with episodic migraine, treatment with Qulipta decreased MMD by 0.7 to 1.7 days as compared to treatment with placebo. In patients with chronic migraine, treatment with Qulipta decreased MMD by 1.8 days as compared to treatment with placebo. In addition, during the clinical trials, patients were allowed to use acute headache treatments (i.e., triptans, ergotamine derivatives, NSAIDs, acetaminophen, and opioids) as needed. These results do not support the implication that Qulipta will result in the complete prevention of migraine headache for all patients. We acknowledge that the TV ad indicates that “You’ll never truly forget migraine” (frames three to four) and that Qulipta “reduces attacks” (frame four); however, this is not sufficient to mitigate the misleading impression.

The TV ad is misleading because the attention-grabbing visuals (e.g., a child climbing down a rope on a playground, a group of children boarding a bus, the chaperone taking a photograph with all the children on the bus which transitions to a woman circling a date on a calendar featuring the picture of the children on the bus) 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 Qulipta, 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 AbbVie, Inc. 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 Qulipta that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Qulipta.

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 903 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 3907 under NDA 215206. 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 05:14:15 PM
On behalf of George Tidmarsh, M.D., Ph.D