DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Thomas Kenney
Director, Regulatory Affairs
Teva Neuroscience, Inc.
145 Brandywine Parkway, Building 300
West Chester, PA 19380

RE: NDA 216354
AUSTEDO® XR (deutetrabenazine) extended-release tablets, for oral use
MA 380

Dear Thomas Kenney:

As part of its monitoring and surveillance program, the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer broadcast advertisement (TV ad), titled "As You Go Spot #2" (AUS-47112), for AUSTEDO® XR (deutetrabenazine) extended-release tablets (Austedo XR).[1] FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Austedo XR 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 protagonist, Dan, showing obvious uncontrollable movements, indicative of tardive dyskinesia (TD). The TV ad emphasizes how uncontrollable movements in the face, mouth, and hands may negatively affect an individual with TD. Dan has involuntary facial movements as he walks to the water cooler. Dan's hands shake as he struggles to both hold down the tap and keep his water bottle under the spigot to fill it with cold water. Austedo XR is then introduced. The post-treatment portion of the TV ad shows Dan smile as he grabs a bright orange travel mug and fills the mug with steaming hot water for tea. Dan continues with his day, demonstrating several actions he can perform without any uncontrollable movements. A prominent feature throughout the TV ad is the bright orange travel mug, carried by Dan in a perfectly steady manner, giving the misleading impression that treatment with Austedo XR will result in constant hand steadiness without any noticeable involuntary body movements.

These presentations misleadingly suggest that Austedo XR provides a greater magnitude of benefit in the treatment of TD than has been demonstrated. According to the CLINICAL STUDIES section of the FDA-approved prescribing information (PI), approval of Austedo XR relied on two studies supporting the use of Austedo in the treatment of TD. The primary endpoint of these studies was the change from baseline in the Abnormal Involuntary

[1] The TV ad "Dan" is available at https://www.ispot.tv/ad/69Sn/austedo-xr-dan (last accessed September 8, 2025).

Movement Scale (AIMS)[2] total score at week 12. The mean AIMS total score in all treatment and placebo groups ranged from 9.4 to 10.1 at baseline. Table 6 in the PI shows that the change from baseline to week 12 in Study 1 was approximately -1.9 relative to placebo (i.e., -3.3 and -3.2 units for the Austedo 36 mg and 24 mg arms, respectively, compared with -1.4 units for placebo). In Study 2, the change from baseline was approximately -1.4 relative to placebo (i.e., -3.0 units for Austedo, compared with -1.6 units for placebo). These results do not correlate with the near-complete resolution of symptoms portrayed in the post-treatment portion of these TV ads. FDA acknowledges that the TV ad includes the SUPER, "Individual results may vary." Furthermore, we acknowledge that the TV ad also includes the SUPER, "In one study, patients taking AUSTEDO 36 mg saw a 33% movement improvement vs 14% for placebo at 12 weeks." However, neither presentation mitigates the misleading impression that patients can expect a near-complete resolution of TD symptoms when taking Austedo XR.

Conclusion and Requested Action

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

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 380 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

[2] The AIMS is a 12-item clinician-rated scale; items 1 to 7 assess the severity of involuntary movements across body regions, and these items were used in the studies. The AIMS total score (sum of items 1 to 7) can range from 0 to 28, with a score of 0 representing no involuntary movements and 28 representing severe involuntary movements in all body regions assessed.

to this letter should be placed under eCTD Heading 1.15.1.6. 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 05:19:25 PM
On behalf of George Tidmarsh, M.D., Ph.D