DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Paul Pisacane
Vice President, Regulatory Affairs
BridgeBio Pharma, Inc.
1800 Owens St., Suite C-1200
San Francisco, CA 94158

RE: NDA 216540
ATTRUBY® (acoramidis) tablets
MA 74

Dear Paul Pisacane:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (MAT-US-ACO-0617) (TV ad) for ATTRUBY® (acoramidis) tablets, for oral administration (Attruby) submitted by BridgeBio Pharma, Inc. (BridgeBio) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus the TV ad misbrands Attruby and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes the following claims (in pertinent part):

- A diagnosis doesn't define you. Even ATTR-cardiac amyloidosis. You've come a long way. Your path was never set in stone. You charged ahead. So, why would life with ATTR-CM define you? You have the power of choice." (Audio voiceover (VO), 00:00 – 00:20)

- "People taking Attruby saw an impact on health-related quality of life…giving you more chances to do what you love with who you love." (Audio voiceover (VO), 00:28 – 00:32; 00:36 – 00:40)

- "IMPACT ON HEALTH-RELATED QUALITY OF LIFE" (SUPER, 0:28)

- "It's time to get busy livin'" (VO, 00:58 – 01:00)

Actor Morgan Freeman speaks to the viewer with the above VO claims as images are shown of an older man smiling as he walks through a high school, attends his retirement party, and then travels to and walks through a national park enjoying time with his grandchild and other family as they watch a geyser about to erupt. During the entirety of the TV ad, an upbeat song is playing in the background that includes the lyrics, "I wish that I knew what I know now, when I was younger, I wish that I knew what I know now, when I was stronger."

The totality of these claims and presentations misleadingly suggests that patients treated with Attruby can be carefree regarding the effects of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) and the burdens commonly associated with the disease or will be able to live as they did prior to their ATTR-CM diagnosis, when this has not been demonstrated in the clinical trial for Attruby. The totality of these claims and presentations also misleadingly suggests that treatment with Attruby will broadly improve a patient's overall quality of life when this has not been demonstrated.

According to the Attruby prescribing information (PI), CLINICAL STUDIES section, "treatment effect of ATTRUBY on functional capacity and health status was assessed by the [six-minute walk distance] 6MWD and the Kansas City Cardiomyopathy Questionnaire-Overall Summary score (KCCQ-OS)." At month 30, both the 6MWD and KCCQ-OS showed a change from baseline, but the change did not show any evidence of improved functional capacity or health status for patients based on these two assessments. Rather the changes from baseline in the assessments showed continued worsening for patients in both the Attruby and placebo arms of the clinical trial through month 30, with Attruby demonstrating a slower rate of decline compared to placebo. ATTR-CM is a chronic and progressively debilitating disease, and while treatment with Attruby may slow the progression of symptoms or functional decline, these data do not support suggestions that treatment with Attruby will relieve patients of concerns or burdens in their daily lives related to ATTR-CM, return them to a state prior to their diagnosis with ATTR-CM, or broadly improve their overall quality of life.

We acknowledge the disclaimer, "Individual results may vary. At the end of the 30-month study of adults taking and not taking Attruby experienced a decline in their KCCQ-OS, a measure of health-related quality of life," presented in conjunction with the claim, "IMPACT ON HEALTH-RELATED QUALITY OF LIFE." However, inclusion of this statement in this promotional communication does not correct or mitigate the misleading suggestions regarding Attruby treatment described above.

Conclusion and Requested Action

For the reasons discussed above, the TV ad misbrands Attruby and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic (FD&C Act).

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that BridgeBio 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 Attruby that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Attruby.

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 74 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 5072 under NDA 216540.

Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

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 05:09:59 PM
On behalf of George Tidmarsh, M.D., Ph.D