DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Inna Kissen, Ph.D.
Senior Director, Promotional Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
Wilmington, DE 19803

RE: BLA 761070
FASENRA® (benralizumab) injection, for subcutaneous use
MA 1274

Dear Dr. Kissen:

The U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television advertisement (TV ad), titled "FASENRA Rachel's Story – End card update" (US-102362) for FASENRA® (benralizumab) injection, for subcutaneous use (Fasenra) submitted by AstraZeneca Pharmaceuticals LP (AstraZeneca) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Fasenra and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

At the beginning of the TV ad, the camera focuses on the patient, Rachel, who makes the following claim:

> Asthma was making me miss out on things I love, like spending time with my kids. My treatment plan was not doing enough for me. I was concerned about future attacks. So, I asked my doctor if we could do more.

The camera then zooms out, revealing a social media post featuring Rachel sitting at home. She then stands up and walks out of the post into an adjacent post featuring a group of people enjoying an outdoor celebration. Concurrent with these presentations, Rachel makes the claim, "[My doctor] ran some tests and recommended adding Fasenra."

Subsequently, Rachel is shown at the outdoor celebration where she claims, "Now I'm breathing better. I haven't had an asthma attack in a year and I'm back to the things I've missed." Then, shown sitting at a soccer game, Rachel states, "Like cheering for my boys." Then, shown working in a store, Rachel states, "Running my shop, and spending time with friends." Towards the end of the TV ad, Rachel is shown hiking with a group of people. Afterwards, Rachel is again shown at the soccer game where she says, "Haven't you missed enough?" She then poses for a selfie with her two sons before the scene becomes a social media post with "likes" popping up in real time from people viewing the post.

The totality of these claims and presentations misleadingly suggests that Fasenra provides greater benefits to patients ages 6 years and older with severe asthma, and with an eosinophilic phenotype than has been demonstrated. Specifically, the compelling before-and-after presentations imply a greater and longer-term improvement in asthma control than has been demonstrated in clinical studies, as well as an improvement in social and emotional functioning. Before Fasenra treatment, Rachel describes herself as someone who misses out on things she loves and is "concerned about future [asthma] attacks." In contrast, after Fasenra treatment, she is portrayed as someone who is no longer concerned about future asthma attacks and has a fulfilling life, involving outdoor celebrations, cheering her sons on at their soccer games, working in her shop, and hiking with other people. The moment with her sons at their soccer game is captured on social media as a photo garnering numerous "likes."

According to the CLINICAL STUDIES section of the Prescribing Information for Fasenra, patients who received Fasenra in the SIROCCO and CALIMA clinical trials did not achieve complete prevention of exacerbations. Additionally, SIROCCO and CALIMA were 48 and 56 weeks in duration, respectively. We acknowledge the claims, "I haven't had an asthma attack in a year" and "Individual results may vary." However, these claims do not mitigate the misleading impression. In fact, the SUPER, "In two studies, 65% and 60% did not have an asthma attack," that is presented concurrently with these claims, further contributes to the misleading impression by omitting the study durations.

Additionally, while Fasenra has been shown to improve the total Asthma Quality of Life Questionnaire for 12 Years and Older (AQLQ(S)+12) responder rate compared to placebo, the clinical studies for Fasenra were not designed to measure the impact of treatment on individual items of the instrument, including those related to social and emotional functioning. Therefore, an improvement in the total AQLQ(S)+12 score does not necessarily correlate with a positive effect on individual components of the score.

The TV ad is misleading because it fails to include material information in the major statement about the advertised drug in the manner required for TV ads for human prescription drugs.[1] Specifically, information regarding hypersensitivity reactions is included only in the SUPERs. The TV ad fails to communicate in the audio that patients should tell their healthcare provider or get emergency help right away if they have symptoms of an allergic reaction, as conveyed in the Patient Package Insert for Fasenra.

The major statement includes presentations where the verbatim complete transcript or verbatim key terms or phrases from the corresponding audio do not appear in dual modality, along with presentations where there is information in the SUPERs that is not from the corresponding audio. Therefore, the TV ad is misleading because it fails to present the major statement concurrently using both audio and text (dual modality).

Conclusion and Requested Action

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

[1] 21 CFR 202.1(e)(1)(i)(A).

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

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 1274 in addition to the BLA 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 1466 under BLA 761070. Questions related to the submission of your response letter should be emailed to the OPDP RPM at 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 05:19:02 PM
On behalf of George Tidmarsh, M.D., Ph.D