



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 1157

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 TV 30 SALSA" (US-95912) 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).

Frames one and two of the TV ad include a social media post comprising an image of a woman sitting bored at home in conjunction with the on-screen text, "**LOSING MY GROOVE. THANKS, ASTHMA**" (emphasis original), presented as a meme. In frames three through four, the woman stands up and walks out of the post, pulled by her friend into an adjacent post featuring a group of her friends who are salsa dancing outdoors. Concurrently, the voice-over claim, "Asthma. Does it have you missing out on what you love, with who you love? Get back to better breathing with FASENRA. . ." is presented in frames one through four. Subsequently, in frames five through nine, the woman is shown dancing and laughing with her friend. In frames 14 to 15, the woman and her friend are shown taking a selfie together 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 an improvement in social and emotional functioning. Before Fasenra treatment, the woman is described and presented as bored, stuck at home, and "losing [her] groove." In contrast, after Fasenra treatment, she is portrayed as someone with an active social life, involving salsa dancing, that is captured on social media as a photo garnering numerous "likes." 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.

Frames three through seven include a SUPER at the bottom conveying information regarding the indication as well as the dosing and administration regimen for Fasenra. However, the presentation of this SUPER is undermined by multiple, competing presentational aspects (i.e., fast-paced salsa dancing and music) that distract the viewer from this information about Fasenra and therefore, create a misleading impression about the drug's efficacy.

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.<sup>1</sup> 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).

Furthermore, the TV ad is misleading because the attention-grabbing visuals and background music (i.e., fast-paced salsa dancing and music) during the presentation of the major statement interfere with comprehension of the major statement.

## **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).

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.

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<sup>1</sup> 21 CFR 202.1(e)(1)(i)(A).

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 1157 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 1344 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](mailto: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

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**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.**  
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/s/  
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On behalf of George Tidmarsh, M.D., Ph.D