DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Purve Patel, Head of US Regulatory Affairs
argenx US, Inc.
33 Arch Street, 32nd Floor
Boston, MA 02110

RE: BLA 761304
VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc) injection, for subcutaneous use
MA 424

Dear Purve Patel:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer television advertisement (TV ad), (US-VYV_HYT-25-00032) for VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc) injection, for subcutaneous use (Vyvgart Hytrulo) submitted by argenx US, Inc. (argenx) under cover of Form FDA 2253. FDA has determined that the TV is false or misleading. Thus, the TV ad misbrands Vyvgart Hytrulo 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 and presentations (emphasis original):

- A man in a coffee shop stating, “It’s my treatment, my way” with the SUPER (emphasis original), “VYVGART Hytrulo **self-injection for treatment MY way”** followed by a coffee shop barista carrying a cup of coffee labeled “WEEKEND AWAY Steve” and stating, “Vyvgart Hytrulo, for weekend-away Steve.” This is followed by the same man, now walking with his family on a walkway at the top of a mountain range, stating, “It’s travel ready, and can go where I go” with the SUPER (emphasis original), “VYVGART Hytrulo **self-injection can go where I go.”**

- A woman in a coffee shop stating, “Self-injection fits my plans” with the SUPER (emphasis original), “VYVGART Hytrulo **A self-injection that can fit MY plans”** and a coffee cup labeled “FOOTBALL FAN Sarah.” This is followed by the same woman tailgating in the parking lot of a stadium.

These claims and presentations are misleading because they suggest that the administration of Vyvgart Hytrulo can be easily completed while traveling or attending an outdoor sporting event, thereby oversimplifying the administration process. The FDA-approved Instructions for Use (IFU) for Vyvgart Hytrulo includes a number of detailed steps required for proper administration of the product, including letting the product sit on a clean, flat surface for 30 minutes to come to room temperature, gathering necessary supplies (e.g., safety needle,

alcohol swab, sharps disposal container, sterile gauze or small adhesive bandage), washing hands, injecting the medication into the abdomen, and disposing the syringe in a sharps container. We acknowledge that a small SUPER appears at the bottom of the screen stating, "Travel ready in its original carton. See Patient Information and Instructions for Use," however, this does not mitigate the misleading impression.

The TV ad is also misleading because it includes claims and presentations about the uses and benefits of Vyvgart Hytrulo but omits material risk information pertaining to the warning and precautions for hypersensitivity reactions and infusion/injection-related reactions. Specifically, the major statement does not communicate the following from the "**What are the possible side effects of VYVGART HYTRULO?**" section of the Patient Information (in pertinent part; underlined emphasis added):

- "Allergic reactions: …get emergency help right away if you have any of the following symptoms of an allergic reaction: rash, swelling of the face, lips, throat or tongue, shortness of breath, trouble breathing, low blood pressure, fainting"

- "Infusion or injection-related reactions: …Tell your healthcare provider if you have any of the following symptoms of an infusion or injection-related reaction: high blood pressure, chills, shivering, chest, stomach, or back pain"

The TV ad is misleading because the attention-grabbing visuals (e.g., zooming effect into a close-up of food cooking on a grill followed by a woman at a tailgating event in a stadium parking lot with friends, a woman looking at a robotic arm with several other people, a man walking with his family and then taking a selfie on a path on top of a mountain range) 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 Vyvgart Hytrulo 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 argenx 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 Vyvgart Hytrulo that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Vyvgart Hytrulo.

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 undersigned at 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 424 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 5419 under BLA 761304. 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}

Lindsay McCann, PharmD, BCCCP
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Taylor Burnett Mmagu, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

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/

LINDSAY M MCCANN
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TAYLOR B BURNETT MMAGU
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