DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Michaelle Exhume, Manager
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

RE: BLA 761063
EMGALITY (galcanezumab-gnlm) injection, for subcutaneous use
MA #558

Dear Ms. Exhume:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communications, two distinct direct-to-consumer broadcast television advertisements, "The Journey Forward: Ryan Murphy" (Ryan Murphy TV Ad) and "The Journey Forward: Allysa Seely" (Allysa Seely TV Ad) for EMGALITY (galcanezumab-gnlm) injection, for subcutaneous use (Emgality). These television advertisements (TV ads)[1] make false or misleading claims and/or representations about the risks associated with Emgality and omit other material facts. Thus, the TV ads misbrand Emgality within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act) and make its distribution violative. 21 U.S.C. 352(n); 321(n); 331(a). 21 CFR 202.1(e)(1); (e)(3)(ii); (e)(5). In addition, these materials were not submitted at the time of initial dissemination or publication as required by 21 CFR 314.81(b)(3)(i). These violations are concerning from a public health perspective because the promotional communications create a misleading impression about the safety and effectiveness of Emgality.

Background

Below are the indication and summary of the most serious and most common risks associated with the use of Emgality[2].

[1] Under 21 CFR 202.1(e)(2), certain advertisements (ads), including reminder ads, are exempt from the requirements of 21 CFR 202.1(e)(1). Reminder ads are defined at 21 CFR 202.1(e)(2)(i) as "those which call attention to the name of the drug product but do not include indications . . . for use of the drug product." Rather, they "shall contain only the proprietary name of the drug product, if any; the established name of each active ingredient in the drug product; and, optionally, information relating to quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug product." As discussed further in this letter, the TV ads addressed herein do not meet the requirements for the reminder ad exemption because they contain representations or suggestions relating to an indication for use of the advertised product (Emgality) and, therefore, must comply with the requirements of 21 CFR 202.1(e)(1).

[2] This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional communication(s) cited in this letter.

According to the FDA-approved product labeling (PI):

> EMGALITY is indicated for the preventive treatment of migraine in adults.
>
> EMGALITY is indicated for the treatment of episodic cluster headache in adults.

Emgality is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of its excipients. The PI contains a warning and precaution regarding hypersensitivity reactions. Cases of anaphylaxis and angioedema have also been reported in the postmarketing setting. The most common adverse reactions are injection site reactions.

False or Misleading Risk Presentation

Prescription drug advertisements and labeling (promotional communications) misbrand a drug if they are false or misleading with respect to risk. The determination of whether a promotional communication is misleading includes, among other things, not only representations made or suggested in the promotional communication, but also the extent to which the promotional communication fails to reveal facts material in light of the representations made or with respect to consequences that may result from the use of the drug as recommended or suggested in the promotional communication.

The TV ads, which state "brought to you by Emgality proud partner of Team USA," (underlined emphasis added) contain claims and/or representations about the use and/or benefits of Emgality. For example, these TV ads include the following claims:

- "I do a whole bunch of different things to try to prevent migraine because for me the pain is really tough" (Ryan Murphy TV Ad)
- "I've leaned on all kinds of doctors and professionals for help" (Ryan Murphy TV Ad)
- "When I was younger, I used to say that my brain hurt" (Allysa Seely TV Ad)
- "By the time I was in college, migraine had me hiding from light and sound, it was isolating" (Allysa Seely TV Ad)

Because the TV ads contain representations or suggestions relating to an indication for use of a particular drug product (Emgality), they are required to include risk information as well. TV ads for prescription drugs are required to include information relating to the major side effects and contraindications of the advertised drug in the audio or audio and visual parts of the presentation and, unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the presentation, to contain a brief summary of all necessary information related to side effects and contraindications.

However, the TV ads fail to communicate **any** risk information about the product. By omitting the major side effects and contraindications associated with Emgality, the TV ads fail to provide material information about the consequences that may result from the use of the drug and create a misleading impression about the drug's safety. The TV ads also fail to either provide adequate provision or a brief summary as required by 21 CFR 202.1(e)(1).

Omission of Material Facts

The TV ads are misleading because they fail to provide material information regarding Emgality's full FDA-approved indication. Specifically, the INDICATIONS AND USAGE section of the PI states the following (underlined emphasis added):

> EMGALITY is indicated for the preventive treatment of migraine in adults.

The Ryan Murphy TV Ad suggests the use of Emgality for the preventive treatment of migraine, but it does not specify that Emgality is indicated for use in adults. The Allysa Seely TV Ad suggests the use of Emgality for the treatment of migraine, but it does not specify that Emgality is indicated for the preventive treatment of migraine in adults. By failing to adequately communicate the indication for Emgality, the TV ads create a misleading impression about the drug's FDA-approved indication.

Failure to Submit Under Form FDA-2253

FDA regulations require any labeling or advertising devised for promotion of the drug product to be submitted at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. A copy of each TV ad was not submitted to OPDP under cover of Form FDA-2253 at the time of initial publication as required by 21 CFR 314.81(b)(3)(i).

Conclusion and Requested Action

For the reasons discussed above, the TV ads misbrand Emgality within the meaning of the FD&C Act and make its distribution violative. 21 U.S.C. 352(n); 321(n); 331(a). 21 CFR 202.1(e)(1); (e)(3)(ii); (e)(5). Furthermore, Eli Lilly and Company did not comply with 21 CFR 314.81(b)(3)(i).

This letter notifies you of our concerns and provides you with an opportunity to address them. OPDP requests that Eli Lilly cease any violations of the FD&C Act. 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 Emgality that contain representations like those described above, and explaining any plan for discontinuing use of such communications, or for ceasing distribution of Emgality.

If you believe that your product is 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. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g., a sticker) to indicate that the submission is intended for OPDP. Please refer to MA 558 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.

Sincerely,

{See appended electronic signature page}

Nima Ossareh, PharmD, RAC
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Sam Skariah, 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/

NIMA OSSAREH
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SAMUEL M SKARIAH
12/13/2021 09:05:36 AM