



Michaëlle 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 completed its review of the information submitted by Eli Lilly and Company (Eli Lilly) on December 21, 2021, in response to the Untitled Letter, issued on December 13, 2021. After review of the information submitted and Eli Lilly's reasoning, as well as the actions taken by Eli Lilly upon receipt of the Untitled Letter, OPDP believes that the concerns contained in the Untitled Letter have been addressed.

Background

As noted in the Untitled Letter, OPDP reviewed two distinct direct-to-consumer broadcast television advertisements (TV ads) for EMGALITY (galcanezumab-gnlm) injection, for subcutaneous use (Emgality): "The Journey Forward: Ryan Murphy" and "The Journey Forward: Allysa Seely." On December 13, 2021, FDA notified Eli Lilly of concerns that the Agency had with the TV ads in an Untitled Letter and provided Eli Lilly with an opportunity to address them. These concerns included that the TV ads made false or misleading claims and/or representations about the risks associated with Emgality that misbranded it within the meaning of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and made its distribution violative. FDA requested that Eli Lilly submit its reasoning and any supporting information if Eli Lilly believed that Emgality was not misbranded within the meaning of the FD&C Act.

On December 21, 2021, OPDP received Eli Lilly's "Response to Untitled Letter" in which Eli Lilly provided additional clarifying information.

According to Eli Lilly, the TV ads that were the subject of the Untitled Letter were intended to be displayed as part of a "complete TV broadcast" consisting of three components. The first component (component 1) included disease state information concerning migraines; this was immediately followed by a second component (component 2) that was presented in the format of a reminder advertisement for Emgality; and, finally, the third component

(component 3) was a full product TV segment for Emgality (including indication and risk information). Eli Lilly stated that these components were intended to be aired on broadcast television together in immediate, sequential fashion. Eli Lilly suggested that all three components should be viewed in totality. However, no “complete TV broadcast” as described by Eli Lilly was submitted to OPDP. Eli Lilly acknowledged that its approach to submitting components to OPDP at the time of initial dissemination, as required by 21 CFR 314.81(b)(3)(i), may have contributed to confusion.

Discussion

FDA has reviewed the reasoning and supporting information Eli Lilly submitted in response to the concerns outlined in OPDP’s Untitled Letter and offers the following:

- The TV ads cited in OPDP’s Untitled Letter (which consist of what Eli Lilly describes as components 1 and 2) included a clear beginning, middle, and end to the presentation. Both ads begin with a banner and voiceover artist stating, “Lilly presents The Journey Forward” and end with a similar banner and the same voiceover artist stating, “The Journey Forward, brought to you by Emgality.” Content between these bookends include presentations from either Ryan Murphy or Allysa Seely. Both TV ads begin with background music that plays continuously from the opening banner and voiceover through the middle content, closing banner, and closing voiceover statement. The music stops and the screen then fades to black at the end of what Eli Lilly describes as component 2, indicating the conclusion of one presentation and the beginning of a separate, potentially unrelated presentation. Each of the two TV ads cited by OPDP appeared as a cohesive presentation.
- In both TV ads cited by OPDP, this impression of one, unified presentation in each case was further enhanced by the similar presentational elements utilized, such as the same background theme, style, voiceover artist, and color for the opening and closing of the presentation. The overall impression from these techniques is of one cohesive TV ad for each of the TV ads cited by OPDP. As noted in the Untitled Letter, because the TV ads cited contained representations or suggestions related to an indication for use of a particular drug (Emgality), they were required to comply with the requirements of 21 CFR 202.1(e)(1).
- Eli Lilly acknowledges it did not submit either of the two “complete TV broadcasts” to OPDP. What Eli Lilly describes as components 2 and 3 were individually submitted on FDA Form 2253 independent of each other, and neither submission referenced coordination with any other communication.
- We note that the Emgality full product TV ad described in Eli Lilly’s response as component 3 (Olympic TV Ad – Silent Struggle) was submitted to OPDP prior to dissemination for comment. However, that submission did not indicate that the full product TV ad was to be disseminated with or as part of any coordinated, sequentially broadcast communications.

Conclusion

We acknowledge and appreciate Eli Lilly's statements that there was an intent to create complete TV broadcasts comprised of three components airing in immediate, sequential fashion. We also acknowledge that Eli Lilly has discontinued use of the "complete TV broadcasts," which included the TV ads (components 1 and 2) cited in the Untitled Letter. In addition, in response to the Untitled Letter, Eli Lilly asked (b) (4) to remove the TV ads cited in the Untitled Letter (consisting solely of components 1 and 2) from its website, and (b) (4) did so. Therefore, OPDP believes that the concerns contained in the Untitled Letter have been addressed, and we consider this matter closed.

FDA reminds you that it is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations, including the requirement to submit a copy of any promotional communication, *in its entirety*, at the time of initial dissemination on Form FDA-2253. FDA reminds Eli Lilly that any advertisement may be submitted to FDA prior to publication for comment. This would include any similar, proposed promotional communication campaigns as they are described in Eli Lilly's December 21, 2021, response letter.

If you have any questions or comments, 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.

Sincerely,

{See appended electronic signature page}

Nima Ossareh PharmD, RAC
Regulatory Review Officer
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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