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21 December 2021

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

RESPONSE TO UNTITLED LETTER

RE: BLA761063; Emgality® (galcanezumab-gnlm); eCTD sequence No. 0752

This letter responds to the Untitled Letter issued by FDA's Office of Prescription Drug Promotion (OPDP) to Eli Lilly and Company (Lilly) on December 13, 2021, regarding communications for Emgality® (galcanezumab-gnlm) described in the Untitled Letter as "The Journey Forward: Ryan Murphy" and "The Journey Forward: Allysa Seely." The Untitled Letter alleges that the communications include false or misleading risk presentations and omit material facts, and that Lilly failed to submit the communications as required under cover of Form FDA-2253. It appears that the letter is based on a misunderstanding of the content and format of the advertisements as they were intended to air (and actually aired) on television. Viewing the advertisements as designed and aired on television, Lilly believes that it did not fail to communicate necessary information as alleged by OPDP or otherwise misbrand Emgality within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act). Lilly therefore requests that OPDP rescind the Untitled Letter.

Prior to addressing FDA's specific objections described in the Untitled Letter, Lilly clarifies the facts surrounding the communications referenced in the Untitled Letter related to the migraine disease state and Emgality and provides a detailed account of the complete TV broadcasts.

The complete TV broadcasts as designed and aired included three components: Component 1: migraine disease state information (presented by an Olympic athlete, either Ryan Murphy or Alyssa Seely), which made no reference to the product name; Component 2: an Emgality "billboard" screen, which was a reminder ad referring to the product but containing no information about its indication; Component 3: Emgality full-product TV segment (including indication and risk information). Lilly provided explicit instructions to the TV network requiring all three components be aired together sequentially. Lilly has confirmed that each airing of the TV broadcast content did, in fact, contain all three components airing in immediate, sequential fashion.

The content the Untitled Letter refers to as "The Journey Forward: Ryan Murphy" and "The Journey Forward: Allysa Seely" in fact comprises only Components 1 and 2 and therefore is not representative of the complete and actual broadcast content aired by Lilly. Components 1 and 2 were not designed to air (and did not air on live TV) without Component 3. Subsequent investigation has revealed that, without Lilly's direction, these Components 1 and 2 appear to have been available for a limited time on (b) (4) [1] without Component 3. Lilly has, however, confirmed that Components 1 and 2 were never aired together on TV without Component

[1] (b) (4) Lilly did not ask (b) (4) to host Components 1 and 2 without Component 3. Nevertheless, on December 14, 2021, Lilly asked (b) (4) to remove Components 1 and 2, without Component 3, from its website. On December 16, 2021, (b) (4) confirmed that those communications no longer appear on the site.

3. Thus, as designed, the content that is the subject of the Untitled Letter was immediately followed in every broadcast by a full product-branded segment for Emgality (Component 3), which included the full indication and major statement of risk. Importantly, the proximity, sequential nature, and thematic elements (including athletes) across the components of the broadcast content was intended by Lilly to indicate that these components should be viewed in totality. Thus, to the extent OPDP believes the athlete statements in Component 1 constitute implied product claims, Lilly's position is that these claims are well-balanced by the clear disclosure of the full product indication and major risks communicated in Component 3 of the broadcast content.

False or Misleading Risk Presentation

The Untitled Letter asserts that "the TV ads fail to communicate **any** risk information about the product" (emphasis original) and that "the TV ads also fail to either provide adequate provision or brief summary." Because Component 3 of the broadcast content (an Emgality product-branded segment) included a major statement of risk highlighting the most important product risk information, Lilly believes that the full advertisement as designed and aired provided the necessary risk content. Further, Lilly believes that the content included adequate provision for product labeling with the disclosure of an internet web page (URL) address that provides access to product labeling and directs consumers to speak with a healthcare professional for more information.

Omission of Material Facts

FDA's communication asserts "the TV ads are misleading because they fail to provide material information regarding Emgality's full FDA-approved indication." As with the risk information, the full indication appeared in Component 3 of the broadcast content promptly after the Emgality logo was displayed in Component 2. Lilly's position is that the full advertisement with all three components in sequence therefore provided the full FDA-approved indication. Alternatively, if FDA views the components separately, Lilly believes that each individual component was compliant with FDA regulations. Lilly submits that the full indication and risk information were not required in Components 1 or 2, because Component 1 contains appropriate disease state awareness information, and Component 2 is a proper reminder ad.

Failure to Submit Under Form FDA-2253

Each of the three broadcast components was developed as a separate file that could be shown separately in compliance with FDA regulations; however for purposes of these broadcasts, these components were intended to air only in sequential fashion. Component 1 did not contain a reference to Emgality and thus the file was not submitted to OPDP on Form FDA-2253. Although Lilly believes that Component 1 did not require submission standing alone, Lilly acknowledges that its submission approach may have contributed to confusion, because it was not clear to OPDP that additional content would be aired directly before Components 2 and 3. The two components with product reference (Components 2 and 3) were submitted at the time of initial dissemination as required by 21 CFR 314.81(b)(3)(i). (Component 2 was submitted on June 2, 2021 [eCTD Sequence 0676]; Component 3 was submitted on June 7, 2021 [eCTD Sequence 0678].)

Conclusion and Response to Requested Action

Lilly is committed to developing and bringing to the US market innovative pharmaceutical products that will improve the health and quality of life for patients. In so doing, Lilly endeavors to work in

partnership with the FDA to understand and comply with the Act, and FDA regulations and policies, including those related to advertising and promotion. Lilly continuously examines its policies and procedures to ensure they comply with FDA regulations and will certainly work with FDA to resolve the concerns cited in the referenced Untitled Letter.

The content cited in the Untitled Letter was disseminated as part of TV broadcasts that included Components 1, 2, and 3 during the Summer Olympic games from July 26, 2021, through September 5, 2021 (four total airings for each advertisement with all three components), which have been discontinued. Because the Untitled Letter cited to a purported advertisement that was not in fact run on television, Lilly does not have any similar pieces to report.

For the foregoing reasons, and given that the full indication and appropriate risk information were provided each time that all three components of the pieces aired on television, Lilly requests that OPDP rescind the Untitled Letter.

This submission, sent via the FDA Electronic Submissions Gateway, has been scanned for viruses using an up-to-date version of the McAfee Antivirus software. For electronic submission technical questions, please contact Vickie Bushard at (317) 655-7045 or bushard_vickie_e@lilly.com.

Again, Lilly takes FDA's objections seriously and is committed to adhering to all promotional laws and regulations. Lilly hopes this response provides the necessary information to address fully FDA's concerns. If you would like to discuss further, please feel free to contact me directly. Thank you for your collaboration and assistance.

Sincerely,
ELI LILLY AND COMPANY

(b) (4)

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