DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Sydney Claud
Associate Regulatory Affairs Specialist
kaleo, Inc.
111 Virginia Street
Richmond, VA 23219

RE: NDA 201739
AUVI-Q® (epinephrine injection, USP), for intramuscular or subcutaneous use
MA 1021

Dear Sydney Claud:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a social media post (post) for AUVI-Q® (epinephrine injection, USP), for intramuscular or subcutaneous use (Auvi-Q) submitted by kaleo, Inc. (Kaleo) under cover of Form FDA 2253. The Form FDA 2253 submitted by Kaleo states that "piece CM-US-AQ-3329 will be hosted within piece CM-US-AQ-3336" as a post.[1] The post was made by Brittany Mahomes on her personal Instagram account in "[p]aid partnership with **auvi-q**" (emphasis original).[2] This post is false or misleading in that it presents information about the benefits of Auvi-Q but fails to include any risk information about the drug. Thus, the post misbrands Auvi-Q within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). *See* 21 CFR 202.1(e)(5). This violation is concerning from a public health perspective because it creates a misleading impression about the safety of Auvi-Q, a drug used to treat patients, including infants and children, with life-threatening allergic reactions who are at increased risk of adverse outcomes, including death.

Background

Below are the indication and summary of the most serious and most common risks associated with the use of Auvi-Q.[3] According to the INDICATIONS AND USAGE section of the FDA-approved Prescribing Information (PI) (in pertinent part):

> AUVI-Q® is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects . . . and biting insects . . . allergen

[1] CM-US-AQ-3329 was submitted as the video portion of the post and CM-US-AQ-3336 was submitted as the text portion of the post.
[2] Posted on Brittany Mahomes' verified Instagram page (https://www.instagram.com/reel/C2fa3XzLxvB/). Last accessed July 16, 2024.
[3] 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.

> immunotherapy, foods, drugs, diagnostic testing substances . . . and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.
>
> AUVI-Q is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions . . .
>
> AUVI-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care.

The PI for Auvi-Q includes warnings and precautions regarding emergency treatment, injection-related complications, serious infections at the injection site, allergic reactions associated with sulfite, and disease interactions. Common adverse reactions to systemically administered epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and respiratory difficulties.

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 post is misleading because it presents efficacy claims for Auvi-Q but fails to communicate **any** risk information. For example, the post includes the following claims:

- "So, I have an infant and a toddler both who have severe food allergies . . . . Based on my experience, I can tell you that a severe reaction may not look how you think it should look. So, after the diagnosis, a big part of the plan was going to my pediatrician, and he did prescribe me Auvi-Q. Auvi-Q is the only epinephrine autoinjector out there for infants and toddlers." (AVO, video portion of post)
- "AUVI-q® (epinephrine injection, USP) is for life-threatening allergic emergencies." (SUPER, video portion of post)
- "[S]haring my experience with [my child's] severe allergic reaction to peanuts . . . . partnering with @auvi_q to help spread awareness about severe food allergies in young children and how to best respond . . . . AUVI-q 0.1 mg is for infants and toddlers 16.5-33 lbs." (text portion of post)

The post, however, entirely omits all risk information. We acknowledge that the post includes the statement, "For Important Safety Information, visit @auviq_ISI[.]"[4] However, this does not mitigate the misleading impression created by the omission of risk information.

[4] The FDA Form 2253 submitted with the post states, "a link to the indication and important safety information is provided [within the post]."

By omitting the risks associated with Auvi-Q, the post fails to provide material information about the consequences that may result from the use of Auvi-Q and creates a misleading impression about the drug's safety.

Conclusion and Requested Action

For the reasons discussed above, the post misbrands Auvi-Q within the meaning of the FD&C Act and makes its distribution violative. 21 U.S.C. 352(a), (n); 321(n); 331(a). *See* 21 CFR 202.1(e)(5).

This letter notifies you of our concerns and provides you with an opportunity to address them. OPDP requests that Kaleo ceases 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 Auvi-Q that contain representations like those described above, and explaining your plan for the timely discontinuation of such communications, or for ceasing distribution of Auvi-Q.

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 1021 in addition to the NDA 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 0769 under NDA 201739. Questions related to the submission of your response letter should be emailed to the OPDP RPM at CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Adewale Adeleye, PharmD, MBA
Team Leader
Division of Advertising & Promotion Review 2
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/

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