



September 30, 2026

**Kyle Diamantas, J.D.**

**Interim Commissioner**

U.S. Food and Drug Administration

10903 New Hampshire Avenue

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**Re: Request for prompt and efficient review of the anticipated Anaphylm™ NDA resubmission**

Dear Mr. Diamantas:

On behalf of the Asthma and Allergy Foundation of America (AAFA), the leading patient organization representing the over 106 million people in the U.S. with asthma and allergic diseases, I am writing to underscore that people at risk for anaphylaxis need a broader range of treatment options so they can choose the form of epinephrine they are most likely to carry and use in an emergency. We encourage the U.S. Food and Drug Administration to conduct a prompt and efficient review that reflects the focused nature of the New Drug Application resubmission for Anaphylm™ (dibutepinephrine) sublingual film and to utilize the most efficient review pathway available.

Anaphylm is an investigational product candidate for the treatment of Type I allergic reactions, including anaphylaxis. We urge FDA to recognize the significant and continuing needs of people at risk for anaphylaxis and to complete its review of Anaphylm™ as expeditiously as the evidence and applicable regulatory standards permit.

Nearly 1 in 50 Americans are at risk for anaphylaxis, and prompt administration of epinephrine is essential to reduce the risk of serious, potentially life-threatening complications. For this reason, our community strongly supports continued innovation in epinephrine delivery options. If approved, Anaphylm's small, portable format and simple, needle-free administration could help address some of the practical and psychological barriers that have historically contributed to under-carrying and under-use of epinephrine. Additional treatment options may help ensure that more patients have access to a form of epinephrine that they are willing and able to carry and use in an emergency.

Discomfort with needles, even for a lifesaving medication, is not theoretical. In our 2019 series of reports, My Life with Food Allergies, we included results of a survey of over 1,200 parents of



children with food allergies. Alarming, of the 1,095 parents who reported that their child had ever had a severe reaction, 72% said that for at least one severe reaction, epinephrine was not administered. Of those parents, 12% stated that their or their children's "fear of the auto-injector (the device and/or needle)" was a reason for non-administration. These experiences reinforce the importance of having easy-to-carry and easy-to-use epinephrine options so that patients, caregivers, educators, and bystanders can be better prepared to act during an emergency.

In December 2025, FDA helped convene an important public discussion about the barriers that can prevent timely access to and use of epinephrine. Participants in the Duke-Margolis workshop emphasized the urgency of epinephrine treatment, the need to reduce hesitation, low carriage rates among adolescents and college students, and the potential value of alternative routes of administration. These are not abstract concerns. They affect preparedness in homes, schools, colleges, workplaces, restaurants, airplanes, and other settings where severe allergic reactions may occur.

We understand that FDA must determine the appropriate review classification for any resubmission based on the content submitted. Nevertheless, when a resubmission is focused on addressing discrete deficiencies identified by the Agency and does not materially alter the previously reviewed evidence base, we believe a review process proportionate to that limited scope serves both patient interests and regulatory efficiency.

We understand that the Anaphylm resubmission is expected to address the specific packaging and administration issues identified by FDA. Publicly reported human factors and pharmacokinetic topline findings indicate that revised packaging reduced the median time required to open the pouch from 17 seconds to 3 seconds; the number of participants experiencing difficulty opening the pouch decreased from 26 of 166 to 1 of 105; and incorrect film placement decreased from 20 of 166 to 2 of 105. The company also reported that no participants in the latest human factors study chewed or prematurely removed the film, and that self-administration produced pharmacokinetic results comparable to clinician administration. While these findings remain subject to FDA's independent evaluation, given the targeted nature of the issues being addressed, we respectfully request FDA to:

- assess the resubmission in accordance with its defined scope and the specific deficiencies it is intended to resolve;



- consider the most efficient review classification and process available consistent with the scope of the resubmission while maintaining FDA's rigorous standards for safety, effectiveness, quality, and usability; and
- communicate promptly with the applicant if any additional information is required to complete the review.

This request is not asking FDA to predetermine the outcome of its evaluation or to compromise its scientific standards. Rather, it reflects the urgency experienced by people at risk for anaphylaxis and the importance of a regulatory process that is both rigorous and proportionate to the questions before the Agency.

No single epinephrine product will meet the needs and preferences of every patient, caregiver, or community setting. Expanding the range of FDA-approved options, when supported by the evidence, can help patients and clinicians select the form of epinephrine they are most likely to carry, have available, and use appropriately during an emergency. For that reason, a timely review of Anaphylm following resubmission is a matter of significant interest to the allergy community.

Thank you for your consideration and for FDA's continued work to improve anaphylaxis preparedness, epinephrine access, and public health. Timely regulatory decision-making is important for patients and families who continue to await potential new treatment options for anaphylaxis.

Sincerely,

Kenneth Mendez  
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