FARE
Food Allergy Research & Education

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Jeffrey Shuren, JD, MD
Director, Center for Devices and Radiological Health
U.S. Food & Drug Administration
10903 New Hampshire Avenue, WO66-5431
Silver Spring, MD 20993-0002

Sent via email: jeff.shuren@fda.hhs.gov

Dear Director Shuren,

On behalf of the more than 33 million Americans with life-threatening food allergies, and as an individual suffering with this disease, FARE (Food Allergy Research & Education) continues to be frustrated by the FDA's decision to further delay approval of neffy®, a needle-free epinephrine delivery device. For 36 years, the food allergy community's only treatment option has been to forcefully insert a needle from an epinephrine auto-injector into the thigh of the patient.

FARE appreciates that FDA wants to ensure that neffy® is as efficacious as existing treatment products for anaphylactic reactions. Our community does not want a less effective treatment option over what exists.

At the May 2023 FDA Advisory Committee meeting, neffy®, a needle-free epinephrine delivery device, was overwhelmingly approved by the Advisory Committee for both children (age 6 and above) and adults. Our community believed this innovation would finally come to the more than 10 percent of Americans with life-threatening food allergies, but instead, the FDA has forced us to wait even longer. Given the available data discussed at length during the Advisory Committee meeting, we are concerned and baffled as to why FDA has delayed approval by asking for additional data. Please share with us what led to the FDA's decision to reject the Advisory Committee's approval including any new data or information that you are seeking.

We all wish for data from a perfect clinical trial that compares standard injected epinephrine delivery with neffy®'s nasal epinephrine delivery in patients experiencing anaphylaxis. FARE believes that FDA would agree that there are both ethical concerns and numerous challenges to obtain such data. Even if you could convince hundreds of people with food, insect, or venom allergies to volunteer to experience anaphylaxis, any controlled trial would probably administer injected and intranasal epinephrine in parallel groups. What if such an experiment demonstrates that intranasal might be a bit slower to set in? And maybe the FDA then concludes that intranasal epinephrine is inferior. The opposite is the case given what we know about our food allergy community's lived experience.

Time is of the essence and such an experiment would not factor in the fear, apprehension, and delay we know exist in real-life use of injectable epinephrine. As communicated by those in our community at the May Advisory Committee meeting, many with food allergies fear the needle. This is especially true in children. This fear results in delayed administration of injectable epinephrine. Waiting means that the efficacy is not as robust, and many require a second injection.

The whole point of needle-free epinephrine delivery, whether intranasal or by other routes, is that these eliminate the fear, anxiety, and delay with needles. Without fear, there is little or no hesitation. The proper yet impossible trial would be to expose people with food allergy to their allergen and let them decide how and when to administer epinephrine, hoping that the clinical trial setting would replicate the real world in which those choosing an auto-injector would hesitate but those choosing intranasal would not. Were that to occur, then one would expect that even if the intranasal route were a bit slower to kick in, it would have the advantage of being administered sooner and able to start working well before anaphylaxis progresses to severe.

Would those with allergies to food, insects, or venom who volunteer for such an experiment be representative of everyone else? If a patient feared needles, would they sign up for a study that would induce anaphylaxis and potentially randomize them into the group that required that they use an auto-injector? We doubt it. Such an experiment is a laudable idea, but it fails to reflect reality.

The reality for FARE is that we are committed to doing everything possible to support innovation toward needle-free epinephrine delivery alternatives for the parents, caregivers, teen-agers, and children who carry, use, or rely on epinephrine auto-injectors to treat themselves or their loved ones. Our community has been very vocal and clear about the need for improved and innovative treatment options, both to FDA's May 2023 Advisory Committee and through our 2021 Externally Led Patient-Focused Drug Development (EL PFDD) meeting. As FARE has previously noted, needle phobia is real, and the associated anxiety with use of needles increases the burden of food allergy through delay and apprehensiveness to administer life-saving epinephrine.

Any new situation, any restaurant, any flight, or any school day can induce heightened anxiety. FARE has heard from our community, "If I start to feel something, when should I administer epinephrine?" The dread is there, and the fear is real. We carry it with us, this large, imposing device, and it connotes crisis. It is not the epinephrine; it is the needle.

Having needle-free options allows our community to switch to a completely different mindset. Many in our community describe this change as, "If I start to feel something, it's no big deal because I'll just use a nasal spray." This is not just a difference of peace of mind at the time of administration. This is a peace of mind that people with food allergies would feel every day that they carry neffy® or any other future needle-free innovation.

Real world post-marketing data is an obvious need for ethical reasons to prove the ongoing safety of a needle-free nasal epinephrine option. Why is this approval different? FARE urges FDA to approve neffy® as soon as additional data are delivered to the Agency. Any further delay is robbing our food allergy community of peace of mind and tools to resolve reactions faster. Finally, we urge FDA and food allergy health professionals to inform our community about the risks and benefits of neffy® post-approval.

Sincerely,

Sung Poblete, PhD, RN
FARE CEO

CC: Robert M. Califf, MD, FDA Commissioner
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