



August 17, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
submitted via [regulations.gov](https://www.regulations.gov)

Re: Docket FDA-2021-N-0553, Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders

To Whom It May Concern:

On behalf of the Asthma and Allergy Foundation of America (AAFA), thank you for the opportunity to provide comments on the FDA's proposed guidance regarding evaluation of food allergens. AAFA is the leading patient organization advocating for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. We appreciate the FDA's attention to the large and growing problem of food allergies in the United States. However, we are concerned that the proposed guidance does not go far enough in delineating when FDA will take affirmative steps to apply new allergen labeling requirements.

Over one in ten adults have food allergies,¹ as do 9.3 percent of children, reflecting an increase in prevalence over time.² Food allergies can result in a severe reaction causing anaphylaxis that in rare cases can lead to death, particularly without prompt access to epinephrine.³ Overall, the rate of emergency room visits for food-related anaphylaxis in the U.S. increased by 124% from 2005 through 2014.⁴

Because people with food allergies must avoid exposure to their allergens, FDA's role in regulating allergen labeling is of vital importance to our community. Under the Food Allergen Labeling and Consumer Protection Act (FALCPA), FDA has promulgated and implemented regulations that require clear, plain-language labeling of certain food allergens in packaged foods. These actions have greatly benefited our community, improving health and nutrition and saving lives.

¹ Gupta et al., Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019 Jan 4;2(1)

² Gupta R, Warren C, Blumenstock J, Kotowska J, Mittal K, Smith B. The prevalence of childhood food allergy in the United States: An update. *Ann Allergy Asthma Immunol* (2017).

³ Bock et al., "Further fatalities caused by anaphylactic reactions to food, 2001-2006." *J Allergy Clin Immunol*. April 2007 Volume 119, Issue 4, Pages 1016–1018

⁴ Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005-2014." *J Allergy Clin Immunol Pract*. 2017 Jan - Feb;5(1):171-175.



FALCPA lists eight “major” allergens that were most prevalent at the time of the law’s passage. Unfortunately, many people experience severe allergies to foods that are not on that list.

As the guidance notes, the FDA has multiple overlapping legal authorities to extend allergen labeling requirements beyond the original “major” eight. The proposed guidance reflects an important step towards understanding *how* FDA might analyze data on additional allergens.

However, we are concerned that the proposal does not do enough to identify *when* FDA will in fact take action to apply labeling and other requirements to other allergens. The proposed guidance notes that FDA made prior labeling decisions in response to external requests. However, the timeline for agency response to these requests has been unacceptable. For example, AAFA and other organizations have been advocating for FDA to extend allergen labeling requirements to sesame since 2014, when a formal request was submitted to the agency. After six years, the agency moved forward only with guidance for *voluntary* disclosure.⁵ Ultimately, in the face of the agency’s inaction, Congress mandated sesame allergy labeling by legislation in 2021. Per this legislation, Sesame will become the ninth allergen under FALCPA by January 1, 2023.

In addition to adding allergens, it is important that FDA indicate how the agency will make decisions about refining the current list of major allergens. The top eight allergens were delineated by Congress in FALCPA, but FDA defines each term, through regulation or subregulatory guidance. For example, FALCPA includes “tree nuts” as a major allergen, but FDA specified the scope of what is considered a tree nut in subsequent guidance to industry.⁶ That list includes some items, like coconuts, that are not true member of the “nut” family, and that do not in fact pose an allergen risk to most people living with tree nut allergies. We would appreciate further information from FDA about when and how the agency will reconsider its definition of existing major allergens to better reflect actual allergy prevalence and impact.

Creating a framework for how FDA will consider evidence related to food allergies is crucial, but it is not enough. FDA must exercise its allergen labeling authority proactively. The agency must develop a far more responsive timeline for requests initiated externally. AAFA is well aware that the agency faces a limited budget for food labeling overall, and we have worked continuously to support appropriations increases to support this important work.

In addition, we strongly encourage the FDA to expand its guidance to allergies that are not IgE-mediated. As the proposed guidance notes, food allergens can cause reactions that are

⁵ FDA, “Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry” (2020). Available at <https://www.fda.gov/media/143521/download>

⁶ FDA, FDA Basics for Industry (current as of 2016). Available at <https://www.fda.gov/industry/fda-basics-industry/section-201qq-act-defines-term-major-food-allergen-include-tree-nuts-addition-three-examples>.



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not IgE-mediated or immune mediated at all. Some of these non-IgE-mediated allergies, such as Food protein-induced enterocolitis syndrome or FPIES, cause severe reactions, particularly in infants and young children. The foods that most commonly trigger these reactions are not identical to those most likely to trigger IgE-mediated reactions, and we urge FDA to ensure that your ongoing assessment of allergens expands to help these children and families safely navigate their food choices as well.

Thank you very much for your time and attention. If you have any questions, please contact me at kmendez@aafa.org.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America