March 13, 2026

The Honorable Martin A. Makary, MD, MPH
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Expert Panel on Food Allergies, docket number FDA-2026-N-1925

Dear Commissioner Makary,

On behalf of the undersigned organizations, thank you for the opportunity to provide comments on the Expert Panel of Food Allergies held on February 25, 2026.

Food allergy rates have risen rapidly since the late 1990's. A recent study estimated the global food allergy prevalence is 4.7%, but possibly as high as 8% in the US.[1,2,3] There is not a single cause of food allergy. We wish to highlight certain data for food allergy development, prevention, and treatment to balance the FDA Expert Panel on Food Allergies session.

- The strongest risk factors for the development of food allergy are early life eczema, wheezing, and/or hayfever; delayed food introduction, damaged skin barrier, certain gene sequence variations (e.g. filaggrin), history of food allergy in a parent and/or sibling, parental migration, black race, and non-vaginal birth.[2]

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[1] Sicherer SH, Sampson HA. Food allergy: A review and update on epidemiology, pathogenesis, diagnosis, prevention, and management. J Allergy Clin Immunol. 2018 Jan;141(1):41-58

[2] Islam N, Chu AWL, Sheriff F, Foroutan F, Guyatt GH, Brignardello-Petersen R, Oykhman P, Iorio A, Izcovich A, Morrison KM, Roldan Benitez Y, Couban RJ, Borovsky D, Zhang Y, Ologundudu L, Pasumarthi K, Farooq SF, Tong K, Tang WC, Faisal H, Khalid MF, Asif MS, French S, Waserman S, Chinthrajah RS, Sampson HA, Mustafa SS, Lieberman JA, Järvinen KM, Bailey S, Bégin P, Sicherer SH, Gerdts J, Carver M, Mitchell L, Cleary K, Greenhawt MJ, Wang J, Anagnostou A, Shaker MS, Chandra-Puri A, Fulkerson PC, Wood RA, Chu DK. Risk Factors for the Development of Food Allergy in Infants and Children: A Systematic Review and Meta-Analysis. JAMA Pediatr. 2026 Feb 9:e256105.

[3] Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. Pediatrics. 2018 Dec;142(6):e20181235.

- These risks are mostly observed associations. No parent "causes" their child's food allergy.[2] Children without risk-factors still develop food allergy, and children with such risks may not.
- Current evidence does not support an association between vaccines (or their additives/preservatives) and the development of food allergy.[2]
- There is no strong evidence linking synthetic food dyes, most additives, or GMOs to the development of food allergy. However, two natural dyes, carmine/cochineal extract and annatto, are recognized food allergens.[4,5]
- Early introduction can decrease (but not outright prevent) the chances of developing food allergy. Data are strongest for peanut and egg, with more limited benefit (without harm) for other foods.[6,7,8] Screening for "pre-allergic" infants before introduction is not cost-effective.[9,10] Universal introduction without screening is endorsed in the 2020 Prevention Guidelines from the American Academy of Allergy, Asthma, and Immunology (AAAAI); American College of Allergy Asthma and Immunology (ACAAI); and Canadian Society of Allergy and Clinical Immunology (CSACI).[11] The NIAID and USDA have yet to endorse this approach.

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[4] Greenhawt, M.J. and Baldwin, J.L. (2013). Food Colorings and Flavors. In Food Allergy (eds D.D. Metcalfe, H.A. Sampson, R.A. Simon and G. Lack). https://doi.org/10.1002/9781118744185.ch34

[5] Dunn SE, Vicini JL, Glenn KC, Fleischer DM, Greenhawt MJ. The allergenicity of genetically modified foods from genetically engineered crops: A narrative and systematic review. Ann Allergy Asthma Immunol. 2017 Sep;119(3):214-222.e3.

[6] Du Toit G, Roberts G, Sayre PH, Bahnson HT, Radulovic S, Santos AF, Brough HA, Phippard D, Basting M, Feeney M, Turcanu V, Sever ML, Gomez Lorenzo M, Plaut M, Lack G; LEAP Study Team. Randomized trial of peanut consumption in infants at risk for peanut allergy. N Engl J Med. 2015 Feb 26;372(9):803-13.

[7] Perkin MR, Logan K, Tseng A, Raji B, Ayis S, Peacock J, Brough H, Marrs T, Radulovic S, Craven J, Flohr C, Lack G; EAT Study Team. Randomized Trial of Introduction of Allergenic Foods in Breast-Fed Infants. N Engl J Med. 2016 May 5;374(18):1733-43.

[8] Scarpone R, Kimkool P, Ierodiakonou D, Leonardi-Bee J, Garcia-Larsen V, Perkin MR, Boyle RJ. Timing of Allergenic Food Introduction and Risk of Immunoglobulin E-Mediated Food Allergy: A Systematic Review and Meta-analysis. JAMA Pediatr. 2023 May 1;177(5):489-497.

[9] Greenhawt M, Shaker M. Determining Levers of Cost-effectiveness for Screening Infants at High Risk for Peanut Sensitization Before Early Peanut Introduction. JAMA Netw Open. 2019 Dec 2;2(12):e1918041

[10] Shaker M, Verma K, Greenhawt M. The health and economic outcomes of early egg introduction strategies. Allergy. 2018 Nov;73(11):2214-2223.

[11] Fleischer DM, Chan ES, Venter C, Spergel JM, Abrams EM, Stukus D, Groetch M, Shaker M, Greenhawt M. A Consensus Approach to the Primary Prevention of Food Allergy Through Nutrition: Guidance from the American Academy of Allergy, Asthma, and Immunology; American College of Allergy, Asthma, and Immunology; and the Canadian Society for Allergy and Clinical Immunology. J Allergy Clin Immunol Pract. 2021 Jan;9(1):22-43.e4.

- Prevention guidance has shifted from delayed to early introduction. Recommendations are made with the best data available at the time and are periodically updated. It can be challenging to look back on evolving scientific understanding with the benefit of hindsight. Rather than attributing the rise in food allergy rates to any single factor—such as the timing of food introduction—or to past recommendations, we can recognize that guidance has evolved as new high-quality evidence, including landmark studies on early introduction, has become available. This ongoing refinement reflects a commitment to updating recommendations based on the best data at each stage.[12,13]
- Food allergy can be treated but not yet cured. Both oral immunotherapy and omalizumab raise reaction thresholds, providing protection against unintended ingestion and lowering reaction severity. Epicutaneous immunotherapy and sublingual immunotherapy have shown potential to accomplish the same goals. Treatment may improve quality of life.[14,15,16,17]
- Labeling of the top 9 allergens helps identify risk of ingestion in packaged goods. Global efforts are underway to standardize labeling of unintended allergen presence (precautionary labeling, e.g., "may contain", etc.). The FDA

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[12] American Academy of Pediatrics. Committee on Nutrition. Hypoallergenic infant formulas. Pediatrics. 2000 Aug;106(2 Pt 1):346-9. Soriano VX, Peters RL, Moreno-Betancur M, Ponsonby AL, Gell G, Odoi A, Perrett KP, Tang MLK, Gurrin LC, Allen KJ, Dharmage SC, Koplin JJ. Association Between Earlier Introduction of Peanut and Prevalence of Peanut Allergy in Infants in Australia. JAMA. 2022 Jul 5;328(1):48-56.

[13] Peanut allergy. London: Department of Health; 1998. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment.
http://webarchive.nationalarchives.gov.uk/20120209132957/http://cot.food.gov.uk/pdfs/cotpeanutall.pd

[14] Mustafa SS, Anagnostou A, Greenhawt M. Updates in the Management of Peanut Allergy. Annu Rev Med. 2026 Jan;77(1):281-295. doi: 10.1146/annurev-med-050224-121037.

[15] Anagnostou A, Greenhawt M, Shaker M, Vickery BP, Wang J. Food allergy yardstick: Where does omalizumab fit? Ann Allergy Asthma Immunol. 2025 Jan;134(1):110-121.

[16] Gurel DI, Anagnostou A, Fiocchi A, Sharon C, Sahiner U, Sindher S, Arasi S. New approaches in childhood IgE-mediated food allergy treatment. Curr Opin Allergy Clin Immunol. 2025 Apr 1;25(2):115-122.

[17] Dantzer JA, Shaker MS, Greenhawt M. Evolving Food Allergy Clinical Trials to Become More Patient-Centered. J Allergy Clin Immunol Pract. 2025 Apr;13(4):763-772.

held a session on this topic in mid-February and is considering how to best address the problem.[18,19]

While identifying the root cause(s) of food allergy would be ideal, we are years away from such discovery. However, the recent risk-factors paper provides the most promising hypothesis-generating leads for regulators and investigators to use as outcomes for clinical trials. No single cause bears blame for the food allergy epidemic, including past reversals in policy. Regulators, clinicians, researchers, and patients can work together to advance understanding of food allergy development through a multi-factorial hypothesis grounded in the strongest available evidence-based science. This collaborative approach can help prioritize promising leads while continuing to explore emerging data in a balanced way.

We recommend the US Food and Drug Administration specifically focuses on the following areas within food allergy, which should result in major policy wins:

1) Formally endorse the AAAAI/ACAAI/CSACI Prevention guidelines, which de-medicalizes and simplifies early introduction, helping to facilitate implementation.
2) Add support for early allergenic food introduction to the 0-1 year WIC package.
3) Focus research into further investigating established risk factors for food allergy, while continuing to rely on high-quality evidence for evaluating potential environmental contributors.
4) Continue to support and cultivate a pragmatic developmental pathway for novel food allergy and anaphylaxis treatments, including reassessing current outcome measures.
5) Create a policy or regulatory framework for adapting the ED05 as the recognized global standard threshold for precautionary allergen labeling on packaged goods.

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[18] Turner PJ, Bognanni A, Arasi S, Ansotegui IJ, Schnadt S, La Vieille S, Hourihane JO, Zuberbier T, Eigenmann P, Ebisawa M, Morais-Almeida M, Barnett J, Martin B, Monaci L, Roberts G, Wong G, Gupta R, Tsabouri S, Mills C, Brooke-Taylor S, Bartra J, Levin M, Groetch M, Tanno L, Hossny E, Weber BB, Fierro V, Remington B, Gerdts J, Gowland MH, Chu D, Van Ravenhorst M, Koplin J, Fiocchi A; World Allergy Organization Consensus on the Use of PAL (ACT-UP!) Working Group. Time to ACT-UP: Update on precautionary allergen labelling (PAL). World Allergy Organ J. 2024 Sep 25;17(10):100972.
[19] https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/virtual-public-meeting-and-listening-session-food-allergen-thresholds-and-their-potential

6) Support additional funding for research into mechanistic causes, prevention, and treatment of non-IgE-mediated food allergic diseases such as food protein enterocolitis syndrome and eosinophilic esophagitis.

Sincerely,

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President
American Academy of Allergy, Asthma, and Immunology (AAAAI)

Dr. Cherie Y. Zachary, MD, FACAAI
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Asthma and Allergy Foundation of America (AAFA)

Allergy & Asthma Network (AAN)

American Partnership for Eosinophilic Disorders (APFED)

Campaign Urging Research for Eosinophilic Disease (CURED)

Elijah-Alavi Foundation (EAF)

Food Allergy & Anaphylaxis Connection Team (FAACT)

International FPIES Association (I-FPIES)

The Mast Cell Disease Society (TMS)

US Hereditary Angioedema Association (HAEA)