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Dr. Robert M. Califf Commissioner of Food and Drugs Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993-0002 Submitted via email

Re: Support for Petition Urging FDA to Stop the Practice of Adding Sesame and other Major Allergens to Foods as Means to Address Cross-Contact Risks (FDA-2023-P-0342)

Dear Commissioner Califf,

The undersigned groups submit this letter in support of the petition by Center for Science in the Public Interest (CSPI) requesting that the Food and Drug Administration (FDA) prevent manufacturers from intentionally adding sesame and other major allergens to products when they identify allergen cross-contact risks, by declaring that this practice violates food safety rules. This action is urgently needed to prevent concerning practices that have emerged as industry moves to implement the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, which went into effect on January 1, 2023.

We are concerned that with the implementation of the FASTER Act, many food manufacturers are intentionally adding sesame to products instead of implementing controls to prevent cross-contact risks. This addition of allergens has the potential to increase risks for sesame-allergic consumers, the very opposite of what the FASTER Act intended.

While CSPI identifies five examples in its petition of companies that have publicly admitted to adding sesame to foods, our organizations have also separately observed numerous examples of this practice, and have received complaints from members and stakeholders. We are deeply

concerned that this practice puts individuals with food allergy at risk and limits their access to safe foods.

We are also concerned that this practice has the potential to undermine long-established protections for Americans with food allergies, and urge FDA to take action before more manufacturers in other sectors of the food industry begin applying it. If food manufacturers can evade food safety requirements simply by adding and then declaring trace amounts of allergens, there will be a strong economic incentive to apply this practice more generally to all major food allergens, increasing risks and decreasing safe food access not just for the estimated 1.5 million Americans with sesame allergy, but for all of the nearly 34 million Americans estimated to have food allergies.

Please respond by swiftly granting the CSPI petition,

Signed,

Allergy Advocacy Association
Allergy & Asthma Network (AAN)
AllergyStrong
American Partnership for Eosinophilic Disorders (APFED)
Asthma and Allergy Foundation of America (AAFA)
Campaign Urging Research for Eosinophilic Disease (CURED)
Elijah-Alavi Foundation (EAF)
Food Allergy Research and Education (FARE)
Food Allergy & Anaphylaxis Connection Team (FAACT)
Food Equality Initiate (FEI)
The FPIES Foundation
Food Allergy Science Initiative (FASI)
International FPIES Association (IFPIES)

CC:

Dr. Susan Mayne, Director, Center for Food Safety and Applied Nutrition (CFSAN) Douglas Stearn, Deputy Director for Regulatory Affairs, CFSAN Dr. Patricia Hansen, Deputy Director, Office of Nutrition and Food Labeling, CFSAN Dr. Stefano Luccioli, Allergen Coordinator, Office of Compliance, CFSAN Yinqing Ma, Director, Compliance Policy Staff, Office of Compliance, CFSAN Dr. Tristan Colonius, Deputy Chief of Staff, Office of the Commissioner