



December 21, 2018

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Rockville, MD 20852
Email: CommissionerFDA@fda.hhs.gov

Dear Commissioner Gottlieb:

As organizations working to improve the lives of individuals and families with food allergies, we are writing in response to the FDA's Request for Information to express our strong support of regulatory action to require allergen labeling and appropriate manufacturing practices for sesame.¹

We share the agency's concern regarding the growing prevalence of sesame allergen. Data submitted to the FDA by Dr. Ruchi Gupta and published in *Pediatrics* and *JAMA Open Network* confirms that sesame allergy has become "the ninth allergen," with prevalence ranking just behind those of the top eight allergens covered by current labeling laws and regulations.^{2,3} What's more, sesame allergy can be severe: 32.5 percent of adults with sesame allergy reported having visited an emergency room for a reaction in the past year, more than for any other

¹ FDA, "Sesame as an Allergen in Foods" (Oct. 30, 2018).

www.federalregister.gov/documents/2018/10/30/2018-23635/sesame-as-an-allergen-in-foods

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 Publication information pending.

allergen among adults.⁴ Among children with sesame allergy, 33.6 percent had visited an ER in the past year, making sesame the 4th-highest cause of ER visits for children.⁵

These data confirm the trend we have observed from our grassroots members. Many children and adults have experienced serious reactions to sesame, and these stories have been reflected in numerous individual comments in support of the citizen’s petition submitted to the FDA in 2014 by Center for Science in the Public Interest (CSPI) and leading allergy experts.⁶ Signatories of this letter have also recently submitted over 500 reports to FDA’s CFSAN Adverse Event Reporting System (CAERS).

Clear sesame labeling would be an enormous help to our community. People who are managing “top eight” allergens have benefitted greatly from the clear labeling that the 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA) established. Unfortunately, those with sesame allergy have yet to realize similar benefits. Without labeling requirements, sesame can be hidden under unfamiliar names like “til” or “simsim.” Sesame can also be concealed under “spices” or “natural flavors.” And because it is not required to be labeled as an ingredient, companies often exclude sesame from allergen policies designed to minimize cross-contact risks during manufacturing. As a result, families need to reach out to every manufacturer to ask if products could include undeclared sesame – and often companies can’t or won’t answer. Without information, people have to avoid a far broader set of products or potentially risk exposing themselves or their children to avoidable reactions. Sesame labeling could relieve families of the triple burden of researching, avoiding products, and fearing reactions from unlabeled sesame.

There is currently significant variation in sesame labeling practices across the industry, as documented by CSPI in a recent report.⁷ Some companies – like General Mills⁸ – already apply allergen labeling to sesame, illustrating the feasibility of updating labeling to include this allergen. And many multinational companies already label for sesame in Canada, Australia, New Zealand, and the European Union, where sesame labeling is required by law. We know that companies can do this, but without consistent rules, consumers cannot rely on labels to keep themselves or their children safe.

We therefore ask that the FDA exercise its authority under FALCPA to require food labels to declare sesame, in line with other major allergens. We also ask that the FDA add sesame to the Compliance Policy Guide, which includes standards for manufacturers to address cross contact

⁴ Letter to Scott Gottlieb from Ruchi S. Gupta, MD. Prevalence Data in Support of 2014 Citizen Petition Regarding Allergen Labeling of Sesame, FDA-2014-P-2035. April 2, 2018. www.regulations.gov/document?D=FDA-2014-P-2035-0259.

⁵ Letter to Scott Gottlieb from Ruchi S. Gupta, MD. Prevalence Data in Support of 2014 Citizen Petition Regarding Allergen Labeling of Sesame, FDA-2014-P-2035. April 2, 2018. www.regulations.gov/document?D=FDA-2014-P-2035-0259.

⁶ <https://www.regulations.gov/docket?D=FDA-2014-P-2035>

⁷ Center for Science in the Public Interest. *Seeds of Change*. April 2018. Available at: <https://cspinet.org/sites/default/files/attachment/seeds-of-change-report.pdf>

⁸ General Mills, “Food Allergy Statement.” www.generalmills.com/en/News/Issues/food-allergy-statement

with allergens during food production.⁹ Finally, while the FDA does not currently require allergen declarations in restaurants, we ask that the FDA add sesame to the model Food Code, which recommends allergen trainings for restaurant workers.

Leading physicians and researchers that work with our organizations will be sending information to help FDA answer some of the specific questions in the RFI. In addition, members of our community who are navigating sesame allergies will be submitting answers regarding their experience with sesame labeling. As organizations, we are grateful for the FDA's commitment to keeping consumers safe and stand ready to work with you to make sesame allergen labeling a reality.

Sincerely,

Asthma & Allergy Foundation of America (AAFA)

Allergy and Asthma Network (AAN)

American Partnership for Eosinophilic Disorders (APFED)

Center for Science in the Public Interest (CSPI)

Campaign Urging Research for Eosinophilic Disease Foundation (CURED)

End Allergies Together (EAT)

Food Allergy & Anaphylaxis Connection Team (FAACT)

Food Allergy Research & Education (FARE)

International FPIES Association (I-FPIES)

The FPIES Foundation

⁹ FDA, "CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" (Updated 2005). www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074552.pdf