



February 27, 2017

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

Re: Sesame Labeling on Food Packages – Docket: 2014-P-2035

Dear Sir or Madam:

On behalf of the Center for Science in the Public Interest (CSPI) and the Asthma and Allergy Foundation of America (AAFA), we are pleased to send you this letter requesting your further consideration of adding sesame to the list of ingredients that must be disclosed on food labels, pursuant to the Food Allergy Labeling and Consumer Protection Act.

CSPI is a consumer-advocacy organization whose missions are to conduct innovative research and advocacy programs in health and nutrition, and to provide consumers with current, useful information about their health and well-being. AAFA, founded in 1953, is the oldest and largest nonprofit patient organization dedicated to improving the quality of life for people with asthma, allergies and related conditions through education, advocacy, and research.

In November 2014, CSPI and other parties submitted a Citizen Petition to the Food and Drug Administration (FDA) to request that the agency add sesame to the list of ingredients that must be disclosed on food labels, pursuant to the Food Allergy Labeling and Consumer Protection Act.

In June 2015, the National Academy of Medicine (NAM) formed a committee to prepare a report on the prevalence, severity, and impact of food allergies, as well as the current understanding of food allergy in diagnostics, treatments, prevention, and public policy. The project was sponsored by several public- and private-sector organizations including the AAFA and FDA.

In November 2016, NAM, published a report entitled *Finding a Path to Safety in Food Allergy Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy*.<sup>1</sup> That report includes information relevant to the FDA's decision on whether sesame always should be disclosed on food labels.

As a guiding principle on when foods should be labeled, the NAM report recommends that decisions should be based upon scientific and clinical evidence on the prevalence, severity, and potency of allergies. The report says that "Foods that are known to cause serious allergic reactions are not necessarily included on the label, for example, **sesame** and mustard (Caballero et al., 2002; Dalal et al., 2012) because they are not included in the U.S. list of priority allergens (see Chapter 7)." <sup>2</sup> [emphasis added] The report goes on to say that "The prevalence of sesame seed allergy in the United States appears to be equivalent to the existing eight priority foods or food groups recognized in the United States among children (Gupta et al., 2013)." <sup>3</sup> The report also states:

For example, in the United States, some foods listed by the FDA as tree nuts (i.e. beech nut, butternut, chestnut, chinquapin, coconut, gingko nut, hickory nut, lichee nut, pili nut, shea nut) could be removed from the current priority list based upon the paucity of data or low frequency of allergic reactions. In addition, **evidence of the allergy prevalence and reaction severity to sesame seeds may warrant their inclusion on the priority allergen list in the United States.**<sup>4</sup> [emphasis added]

The committee pointed out, as we did in our petition, that sesame is required to be disclosed on food labels in the European Union, Australia, and Canada.

Furthermore, the NAM report noted that an industry organization, the International Life Sciences Institute, had a task force that studied food allergies:

Following this, a Task Force of the International Life Sciences Institute–Europe (ILSI–EU) conducted a more thorough assessment of foods that warranted placement on a list of priority allergenic foods (Bousquet et al., 1998). The criteria used by the ILSI–EU group included published evidence of severe or fatal anaphylactic reactions. The ILSI–EU Task Force recommended a priority food allergens list that included milk, egg, fish, crustacean shellfish, peanut, soy, tree nuts, wheat, and **sesame seed.**<sup>5</sup> [emphasis added]

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<sup>1</sup> National Academies of Sciences, Engineering, and Medicine. 2016. *Finding a path to safety in food allergy: Assessment of the global burden, causes, prevention, management, and public policy*. Washington, DC: The National Academies Press. doi: 10.17226/23658.

<sup>2</sup> Ibid. p. 232.

<sup>3</sup> Ibid. p. 288.

<sup>4</sup> Ibid. p. 312.

<sup>5</sup> Ibid. p. 284, 286.

We urge the FDA to include sesame among the list of ingredients that must be disclosed on food labels, pursuant to the Food Allergy Labeling and Consumer Protection Act. Thank you again for the opportunity to bring our perspective to your discussions.

Thank you for considering these views.

Sincerely,



Michael F. Jacobson, Ph.D.  
Executive Director  
Center for Science in the Public Interest



Cary Sennett, MD, PhD  
President and CEO  
Asthma and Allergy Foundation of America