

# United States Senate

WASHINGTON, DC 20510

March 20, 2018

The Honorable Scott Gottlieb  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write to request the Food and Drug Administration (FDA) use its existing authorities under the Food Allergen Labeling and Consumer Protection Act (FALCPA) to require products containing sesame seeds and sesame products to be labeled and regulated in a manner similar to the rules that apply to the eight current labeled major allergens.

It has been over a decade since Congress passed the FALCPA, and the landscape of allergy labeling has changed since its passage. Recognizing this, Congress gave FDA the authorities under 21 U.S.C. § 343(x) to promulgate additional regulations requiring allergen disclosure beyond the “Big 8” (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soy) allergens outlined in the original statute. FDA has previously used this authority to require labeling on the coloring carmine/cochineal, due to its role in anaphylactic reactions in allergic people. We urge FDA to use this authority for the labeling and regulation of sesame products. Further, a Citizen Petition—FDA-2014-P-2035, filed by the Center for Science in the Public Interest and a number of prominent allergists and concerned parents in November 2014—has yet to receive a response from FDA. These concerned parents and citizens deserve answers and action, and we urge FDA to take swift action to address the petitioners’ request.

Members of Congress wrote to FDA requesting action in this matter in 2015. Since then, the urgency of FDA action has only increased. A November 2016 report from the National Academies of Sciences found that, “[a]lthough the list of eight priority allergenic foods or food groups established by the CAC remains valid in general, the list has not been reviewed since 1999 and it should be reconsidered now and periodically thereafter...[S]cientific and clinical data regarding the prevalence of allergies to specific foods were insufficient.”<sup>1</sup> Citing current prevalence data, the NAS noted that Canada and the EU both require sesame labeling, and that “[t]he 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....”<sup>2</sup> The report further recommends, “evidence of allergy prevalence and reaction to sesame seeds may warrant their inclusion on the priority allergen list....”<sup>3</sup>

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<sup>1</sup> Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy, *National Academies of Sciences*, Nov. 30, 2016, <http://nationalacademies.org/hmd/reports/2016/finding-a-path-to-safety-in-food-allergy.aspx>.

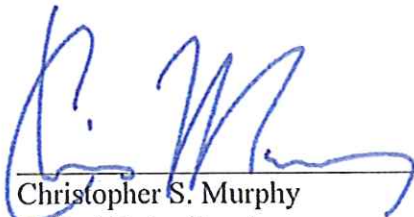
<sup>2</sup> *Id.* at 288.

<sup>3</sup> *Id.* at 312.


The most recent data on food allergies in general, and sesame in particular, demonstrates that the incidence of allergies among U.S. children is increasing, and that sesame is among the most prevalent of allergies, ranking 9<sup>th</sup> in a 2015-2016 survey of 41,000 children.<sup>4</sup> Robert Wood, the director of the division of pediatric allergy and immunology at Johns Hopkins University School of Medicine, notes that sesame allergies “have probably increased more than any other type of food allergy over the past 10 to 20 years.” In addition to its mounting prevalence, sesame poses a particular danger due to the severity of the allergy: for some, sesame exposure can trigger potentially-fatal anaphylaxis. Exacerbating the problem, sesame is often listed using unfamiliar ingredient names, like “tahini” and “gingelly,” or hidden behind a generic label of “spices” or “natural flavors,” while some companies will not disclose the presence or absence of sesame even when directly asked by consumers.<sup>5</sup> Without clarity and uniformity in labeling, sesame-allergic individuals are at great risk of unknowingly consuming sesame and triggering a severe reaction.

Accurate, uniform, and comprehensive allergen labeling is essential to enable allergy sufferers to avoid specific ingredients and potentially fatal reactions. Given the danger and growing prevalence of sesame allergies, as well as new scientific recommendations, we ask FDA to move quickly to require sesame labeling to help protect the health and safety of our constituents.

Sincerely,



Christopher S. Murphy  
United States Senator



Edward J. Markey  
United States Senator



Richard Blumenthal  
United States Senator



Sheldon Whitehouse  
United States Senator



Jack Reed  
United States Senator

<sup>4</sup> “The prevalence of childhood food allergy in the United States: an update,” R. Gupta, *et al.*, *Annals of Allergy, Asthma and Immunology*, Nov. 2017, Vol. 119, Issue 5, Supplement, Page S11, [http://www.annallergy.org/article/S1081-1206\(17\)30728-7/fulltext](http://www.annallergy.org/article/S1081-1206(17)30728-7/fulltext).

<sup>5</sup> “Open Sesame: Why Sesame Must Be Disclosed as an Allergen on Food Labels,” Center for Science in the Public Interest, Sept. 17, 2015.