Congress of the United States Washington, DC 20515

November 27, 2018

Commissioner Scott Gottlieb, M.D. U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We urge the Food and Drug Administration (FDA) to use its existing authority to require the clear labeling of sesame products and products containing sesame seeds, and to regulate such products in a manner similar to the eight currently labeled major allergens.

Sesame is the ninth most common food allergy among American adults and children, ranking just behind the eight allergens for which FDA requires labeling (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans). However, allergic reactions to sesame can be even more severe than reactions to these eight allergens. Among adults with sesame allergies, 32.5 percent report having been to the emergency room (ER) in the past year for an allergic reaction – a higher rate than for any of the eight labeled allergens. Rates of ER visits are even more common among children with sesame allergies.

Despite the prevalence and severity of sesame allergies, current regulations allow sesame to go unnamed on food labels. Even when sesame is named, it can be listed under names that are not easily recognizable to consumers, such as "sim sim" or "til." The absence of a clear label makes it difficult for consumers to identify products that contain sesame, increasing the risk of accidental exposure and allergic reactions.

Aligning sesame labeling requirements with those applied to the aforementioned eight allergens would not impose an undue burden on manufacturers. Manufacturers are already familiar with these requirements for the top eight allergens. Moreover, Canada, Australia, New Zealand, and the European Union require sesame labeling, meaning that multinational manufacturers have already been labeling sesame in other markets.⁴

¹ "The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States." Ruchi S. Gupta, Elizabeth E. Springston, Manoj R. Warrier, Bridget Smith, Rajesh Kumar, Jacqueline Pongracic, Jane L. Holl. *Pediatrics*. July 2011, 128 (1) e9-e17; DOI: 10.1542/peds.2011-0204. http://pediatrics.aappublications.org/content/128/1/e9.

² See 1.

³ See 1.

⁴ "Seeds of Change." Sarah Sorscher, JD, MPH. Center for Science in the Public Interest. April 2018. https://cspinet.org/sites/default/files/attachment/seeds-of-change-report.pdf.

Considering the prevalence and severity of sesame allergies, we strongly encourage the FDA to regulate sesame products in a manner similar to the eight currently labeled allergens and require the clear labeling of these products. Uniform and easily understandable labels will help Americans with sesame allergies and their families safely navigate their food choices and avoid preventable reactions.

We look forward to your response.

Sincerely,

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