



November 24, 2020

Stephen Hahn, 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



Re: Docket No. FDA-2020-D-0530 for “Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry.”

Dear Commissioner Hahn:

As organizations working to protect the health and improve the lives of people with food allergies, we support the FDA’s issuance of draft guidance to industry regarding disclosure of sesame as an allergen.¹ Because of the prevalence and severity of sesame allergy, the risks posed by the lack of labeling, and FDA’s existing authorities to require allergen labeling, we are writing to urge the agency to swiftly act to make sesame allergen labeling mandatory.

Sesame allergy is a serious and growing public health problem.

As the draft guidance notes, the prevalence of sesame allergy makes it the ninth most common food allergy in the U.S., after the “top eight” for which labeling is currently required.^{2,3} Overall, an estimated 1.5 million children and adults in the U.S. may have a current sesame allergy.⁴

¹ FDA, “Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry” (Nov. 2020). Available at <https://www.fda.gov/media/143521/download>. Federal Register notice available at <https://www.federalregister.gov/documents/2020/11/12/2020-24727/voluntary-disclosure-of-sesame-as-an-allergen-draft-guidance-for-industry-availability-agency>

² Ruchi S. Gupta, Christopher M. Warren, Bridget M. Smith, Jesse A. Blumenstock, Jialing Jiang, Matthew M. Davis, Kari C. Nadeau. “The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States.” *Pediatrics* Dec 2018, 142 (6) e20181235; DOI: 10.1542/peds.2018-1235

³ Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630

⁴ Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. *JAMA Netw Open*. 2019;2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144

Severe reactions in sesame-allergic consumers are relatively common, compared to other allergens. About a third of sesame-allergic adults and children experienced an emergency department visit related to any food allergy in the prior year, the highest proportion for any other adult allergy and a higher proportion than that for any other childhood allergy except fin fish, egg, and soy.^{5,6} While sesame has not been confirmed as the cause of all of these visits, perhaps in part because it is not consistently labeled, the data suggest that at a minimum, sesame-allergic consumers are at a high risk for frequent severe food allergic reaction.

The adverse event reports discussed in the FDA draft guidance reflect the experience of our patient communities: severe reactions to sesame exposure are common. And because many of these reactions are to sesame that is not clearly disclosed on product labels, they are preventable.

The current lack of sesame labeling threatens health and creates barriers for consumers.

Children and adults with sesame allergy have yet to benefit from the kind of clear, mandatory allergen labeling required of the “top eight” allergens under the 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA). Sesame ingredients can currently be listed under unfamiliar names like “til” or “simsim.” More commonly, sesame is simply included under a listing of “spices” or “natural flavors.”

Consumers can request more information from specific companies for specific products each time they make a purchase, but this creates an enormous burden, and companies are under no obligation to provide answers. Without clear information about when sesame is present, children and adults with sesame allergy must either avoid a broad set of products or risk severe allergic reactions.

FDA’s legal authority to expand allergen labeling is clear.

As the draft guidance details, FDA currently has the legal authority it needs to make sesame labeling mandatory. Under section 403(i) of the Federal Food, Drug, and Cosmetic Act, FDA has the authority to require that foods bear the “common and usual name” of each ingredient. Under section 403(x), FDA has the authority to order disclosure of spices, flavorings, colorings, or incidental additives that are allergens, beyond the top eight foods that are currently subject to mandatory labeling. These two authorities permit the agency to require mandatory labeling of sesame when it appears either as a listed ingredient or as a “spice” or “flavoring.”

FDA should initiate rulemaking to establish mandatory allergen labeling for sesame.

We strongly urge FDA to initiate rulemaking to *mandate* sesame labeling without delay. Specifically, we urge the FDA to grant in full the Center for Science in the Public Interest’s over six-year old petition requesting the FDA take several actions to protect consumers from undeclared sesame in products.⁷ In particular, in addition to mandating sesame labeling, the petition asked that FDA add sesame to the Compliance Policy Guide, which includes standards for manufacturers to address cross contact with allergens during food production.⁸

⁵ Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630

⁶ Warren CM, Chadha AS, Sicherer SH, Jiang J, Gupta RS. Prevalence and Severity of Sesame Allergy in the United States. *JAMA Netw Open*. 2019;2(8):e199144. doi:10.1001/jamanetworkopen.2019.9144

⁷ Citizen Petition to FDA from CSPI et al., dated Nov. 18, 2014, FDA-2014-P-2035-0001.

⁸ FDA, “CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens” (Updated 2005). Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-statement-policy-labeling-and-preventing-cross-contact-common-food-allergens-new>

Conclusion

The draft guidance is an important step because it signals to manufacturers that they need to begin to address their sesame labeling practices. However, a voluntary system does little to help consumers with sesame allergy. The lack of sesame on a label will not necessarily mean a product is safe – it could simply mean that a manufacturer has chosen not to implement the “recommended” labeling.

We therefore strongly urge the FDA to move quickly, via rulemaking, to mandate allergen labeling for sesame. We are encouraged by FDA’s framing of the voluntary guidance as an “interim” step as the agency works “to develop factors to inform future regulatory actions related to sesame and other emerging food allergens, including possible labeling requirements.” Given the large and growing body of evidence on the prevalence and severity of sesame allergy, the groundwork FDA has already laid through the Request For Information and this draft guidance, and the fact that many manufacturers already label for sesame in Europe, Canada, and other countries,⁹ there should be no further delay in initiating rulemaking for mandatory labeling.

We remain grateful for the FDA’s commitment to protecting consumers with food allergies, and we stand ready to work with you to make sesame allergen labeling mandatory.

Sincerely,

Asthma and Allergy Foundation of America
Allergy & Asthma Network
Allergy Strong
American Partnership for Eosinophilic Disorders
Center for Science in the Public Interest
CURED Foundation
Elijah-Alavi Foundation
Eosinophilic Family Coalition
Food Allergy & Anaphylaxis Connection Team (FAACT)
Food Equality Initiative
International FPIES Association (I-FPIES)
The FPIES Foundation
The Mast Cell Disease Society, Inc.

⁹ “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>.