



February 22, 2021

Janet Woodcock, M.D.
Acting 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 Acting Commissioner Woodcock:

On behalf of the Asthma and Allergy Foundation of America (AAFA), I am writing to express our appreciation of FDA’s voluntary labeling guidance for sesame, and to urge you to immediately take regulatory action to make these changes mandatory.¹

AAFA is the leading patient organization advocating for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. We have seen the growing impact of sesame allergy among our patient community and watched the corresponding increases in national prevalence data. After years of advocating on this issue and bringing our concerns to FDA, we are very glad to see that the agency understands both the prevalence and severity of this allergen. The voluntary guidance is an important step to prepare and educate industry – but the evidence strongly supports FDA using its existing authorities to immediately initiate rulemaking to make sesame allergen labeling mandatory.

AAFA has been working hard to support a policy shift requiring sesame labeling. In 2018, we met with officials from FDA’s Center for Food Safety and Applied Nutrition, or CFSAN, to present our community’s perspective on the growing prevalence and severity of sesame allergy, and to learn how FDA would develop its stance on sesame as an allergen. In response to CFSAN’s request for more information, we administered a survey to our patient community to collect further reports of allergic reactions to sesame, particularly highlighting cases where sesame was not clearly listed on the label. We continued to gather information on patient experience, in collaboration with coalition partners Food Allergy Research and Education (FARE) and the Center for Science in the Public Interest (CSPI), when FDA requested further input through the late 2018 Request for Information on sesame.

On December 12, 2018, AAFA submitted 225 adverse event reports to sesame in sesame allergic consumers to the CFSAN. The reports were collected between October 11, 2018 and December 11, 2018. The vast majority of the adverse events reported occurred between 2003 and 2018, with a single event reported from 1992. Of the reports, 43% resulted in an emergency department visit or hospitalization and 24% of reactions were treated with epinephrine. Over half of the reported reactions were caused by hummus and tahini sauce. The other foods most commonly reported as the cause of a reaction were bread,

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>



crackers, pretzels, and sesame seeds. 46% of the described adverse reactions occurred in association with products that did not have sesame declared on the product label.

All along, our advocacy has pointed to making sesame labeling mandatory. Rulemaking to that end will comply both with science and with the will of Congress, as reflected repeatedly since the draft sesame guidance was released last October. In late 2020, both the House and Senate passed versions of the FASTER Act, which would have directly identified sesame as a top allergen under the Food Allergen Labeling and Consumer Protection Act (FALCPA). Though the session ended before the chambers could work out a compromise over other distinctions between the bills, both would have created a legislative path to mandatory sesame labeling; as FDA has noted, the agency also has the ability to require labeling through other existing authorities. Regardless of what path is ultimately taken, the passage of the FASTER Act in both chambers made clear that Congress believes mandatory sesame labeling is the right policy, and the time is now. As the explanatory statement that accompanied the FY21 appropriations bill passed in December noted:

The agreement is concerned that the recent FDA Draft Guidance for Industry on Voluntary Disclosure of Sesame is insufficient to protect Americans with sesame allergy, and directs FDA to consider further action to require sesame to be labeled the same as other major allergens.²

A summary of the evidence in support of mandatory sesame labeling, detailed below, echoes that presented by AAFA as part of a larger food allergy coalition in our regulatory comments sent November 24, 2020.³

Sesame allergy is a major and growing public health problem.

As the draft guidance notes, the prevalence of sesame allergy makes it the ninth most common in the U.S., after the “top eight” for which labeling is currently required.^{4,5} Overall, an estimated 1.1 million children and adults in the U.S. may have a current sesame allergy.⁶

Severe reactions to sesame are relatively common, compared to other allergens. Among adults with sesame allergy, one in three reported a food-allergy-related ER visit in the prior year, compared to 10% of adults with food allergies overall.⁷ More than a third of all children and adults with sesame as their only food allergy have experienced severe reactions resulting in emergency room treatment.⁸

² <https://docs.house.gov/billsthisweek/20201221/BILLS-116RCP68-JES-DIVISION-A.pdf>

³ Letter from AAFA and 12 additional advocacy organizations to Stephen Hahn (Nov. 24, 2020). Available at <https://www.aafa.org/media/2839/aafa-letter-urging-fda-to-make-sesame-allergen-labeling-mandatory.pdf>

⁴ 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

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 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

⁸ 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



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 have to either avoid a broad set of products or risk severe 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. 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. We also ask that FDA add sesame to the Compliance Policy Guide, which includes standards for manufacturers to address cross contact with allergens during food production.⁹

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 RFI

⁹ 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>



and this draft guidance, and the fact that many manufacturers already label for sesame in Europe, Canada, and other countries,¹⁰ there should be no further delay in initiating rulemaking for mandatory labeling.

AAFA remains 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,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

¹⁰ "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>.