CENTER FOR
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Division of Dockets Management
Food and Drug Administration Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request (Docket No. FDA-2020-D-0530)**

To Whom it May Concern:

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the Food and Drug Administration's (FDA's) Guidance for Industry on the Voluntary Disclosure of Sesame as an allergen.

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government grants or corporate donations. A core part of CSPI's mission is providing consumers with current, useful information about their health and well-being. CSPI publishes the Nutrition Action Healthletter, which provides science-based advice on health and nutrition to hundreds of thousands of readers. CSPI regularly advocates for greater transparency, disclosure, and the safety of food ingredients.

More than six years have passed since CSPI and six allergy experts petitioned the FDA on November 18, 2014,[1] for a rule to protect consumers from undeclared sesame in products.

Since that time, the FDA has failed to provide mandatory protections for the more than 1 million Americans with sesame allergies. Instead, the agency in November 2020 solicited request for comment on a draft guidance providing *voluntary* recommendations to manufacturers regarding what the agency believes are best practices for sesame labeling.[2] Such a guidance falls well short in addressing serious risks to sesame-allergic consumers. The agency should replace the proposed guidance immediately with a proposed rule requiring mandatory sesame labeling.

[1] Petition by Center for Science in the Public Interest to Require Sesame Labeling (Nov. 18, 2014), https://cspinet.org/sites/default/files/attachment/11-18-sesame-petition.pdf [hereinafter Petition].
[2] Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request. 85 Fed. Reg. 71920 (Nov. 12, 2020).

## I. The FDA has Clear Authority to Require Allergen Labeling for Sesame

Accurate and informative labeling is critical for consumers with food allergies because they must strictly avoid specific foods and ingredients to prevent potentially serious reactions. That is why in 2004, Congress enacted the Food Allergen Labeling and Consumer Protection Act (FALCPA) to improve the labeling of food allergens. FALCPA, which amended the federal Food, Drug and Cosmetics Act (FDCA), required that eight "major" food allergens (*i.e.*, milk, eggs, fin fish, shellfish, tree nuts, peanuts, wheat, and soybeans)—the "Big Eight"—must be listed by their ordinary names, such as "milk," either in the ingredients list or under a separate "contains" statement.[3] This requirement means that the Big Eight cannot be concealed under an uncommon name or as a spice, flavoring, coloring, or incidental additive.

In addition to the provisions related to the Big Eight, FALCPA expanded the FDA's authority to require labeling for other food allergens. Under FALCPA, the FDA may specify the manner in which a food allergen other than the Big Eight is disclosed on labels where a "spice, flavoring, coloring, or incidental additive . . . contains . . . a food allergen." [4] FDA previously relied in part on its FALCPA authority in requiring labeling for cochineal extract and carmine as a coloring in foods.[5]

The FDA also has general authority under the FDCA, beyond the amendments in FALCPA, to regulate the labeling of food allergens, including through the FDA's authority to identify and prohibit the sale of misbranded and adulterated foods.

Concerning misbranded foods, the FDA generally has the authority to prevent the interstate sale of foods bearing false or misleading labeling.[6] In determining whether labeling is misleading, the FDA "take[s] into account (among other things) . . . the extent to which the labeling or advertising fails to reveal facts . . . material with respect to consequences which may result from the use of the article."[7] In addition, the food may be deemed misbranded if the label fails to list ingredients by their "common or usual name," which may be established by the FDA through regulation.[8]

The FDCA also authorizes FDA to prevent the interstate sale of adulterated food, that is, food that "bears or contains any poisonous or deleterious substance which may render it injurious to health."[9] The FDA has used this authority to address cross-contact risk (the risks that non-allergen containing foods will contact allergens during the manufacturing process). In 2001, for example, the FDA issued a Compliance Policy Guide (CPG) on food allergen cross-contact.[10] The CPG makes clear that the failure of manufacturers to take proper allergen control measures related to the Big Eight could violate the prohibition on adulterated food.[11] Although the FDA

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[3] 21 U.S.C. § 343(w).
[4] *Id.* § 343(x).
[5] Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration. 74 Fed. Reg. 207 (Jan. 5 2009). That action was also separately supported by the agency's authority to require specific declarations for color additives. *Id.*
[6] *See id.* § 343(a).
[7] *Id.* § 321(n).
[8] *See id.* § 343(i); 21 C.F.R. § 102.5(d).
[9] *Id.* § 342(a).
[10] FDA, Compliance Policy Guide (CPG) Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens (2005).
[11] *Id.* at 2.

has authority to extend the CPG to cover any allergen, the CPG currently covers only the Big Eight.

In addition, the FDA was provided with additional authority under the Food Safety Modernization Act (FSMA), which amended the FDCA to require that food manufacturers identify and implement preventive controls for food safety hazards, including allergens.[12] While FSMA does not specifically identify the allergens that must be addressed as hazards, the FDA has issued regulations defining the term "allergen" to include only FALCPA's "major" food allergens, effectively limiting its food safety regulations to cover only the Big Eight.[13]

Although FALCPA only addresses packaged foods, the FDA issues guidance to encourage best practices at restaurants and other food establishments when dealing with allergens. For example, the FDA publishes the Food Code, a document that serves as a model for state and local government agencies regulating the retail and food service segments of the food industry. The Food Code has contained advice on the Big Eight since 2005.[14]

FDA thus has sufficient authority, through provisions of the FDCA, as amended by FALCPA and FSMA, to issue regulations requiring mandatory labeling for sesame, extending the same protections for sesame as are already offered for the Big Eight.

## II. The Public Health Risks Posed by Sesame Warrant Mandatory Labeling

Sesame poses a public health concern generally similar to the "Big Eight" for which allergen labeling has been federally required since 2006. An estimated 1.1 million people in the United States live with sesame allergy.[15] Sesame can cause severe allergic reactions, including hives, swelling in the face, throat, or mouth, difficulty breathing, and several anaphylaxis. If untreated, anaphylaxis from sesame can result in death.[16]

In 2016, a report by the National Academies of Sciences, Engineering, and Medicine found 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 among children" and concluded that "evidence of the allergy prevalence and reaction severity to sesame seeds may warrant their inclusion on the priority allergen list in the United States."[17]

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[12] *See* 21 U.S.C. § 418(b)(1)(A).
[13] 21 C.F.R. § 117.3.
[14] CSPI, Comment Letter on FDA's Request for Information on Sesame as an Allergen in Foods (Dec. 31, 2018), FDA-2018-N-3809-4592 at 11 [hereinafter December 2018 Letter]; *see also* FDA, Food Code (2017), https://bit.ly/39gHGdN.
[15] Warren C, Chadha A, Sicherer S, Jiang J, Gupta R. *Prevalence and severity of sesame allergy in the United States*. JAMA Network Open. 2019; 2(8): e199144.
[16] Petition (citing, *e.g.*, Ilan Dalal *et al.*, *Sesame Seed Food Allergy*, 12 Current Allergy Asthma Rep. 339 (Aug. 12, 2012)); Ruchi S. Gupta, Comment Letter on Petition (Apr. 2, 2018), FDA-2014-P-2035-0259 at 2; Ido Efrati, *Tourist Dies of Allergic Reaction to Tahini*, Haaretz (Jan. 4, 2014), https://bit.ly/3eknE4W.
[17] *See* CSPI & Asthma and Allergy Foundation of America (AAFA), Comment Letter on Petition (Feb. 27, 2017), FDA-2014-P-2035-0034 (citing National Academies of Sciences, Engineering, and Medicine, Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy 14 (2016), https://bit.ly/2WH6xVx).

Data from a nationwide survey of 53,575 U.S. households between October 2015 and September 2016 estimated that at least 0.2 percent of adults and children have a sesame allergy.[18] Sesame thus ranks ninth in prevalence among adult and childhood food allergies, next in line behind soy (0.6 percent of adults and 0.5 percent of children) and wheat (0.8 percent of adults and 0.5 percent of children).[19]

The survey also showed that children with a sesame allergy were more likely to report a severe food allergy (defined as a reaction involving multiple organ systems) than children with an allergy to milk, which is ranked second in prevalence.[20] Adults with a sesame allergy were more likely to report a severe food allergy than adults with an allergy to milk and egg, which are ranked third and sixth in prevalence, respectively.[21] Indeed, according to the survey, 27.2 percent of sesame-allergic children and 39.7 percent of sesame-allergic adults in the United States have experienced a severe allergic reaction from sesame.[22]

Because sesame is not a member of the Big Eight, however, FDA regulations do not require sesame to be specifically identified on food labels. For example, FDA regulations allow sesame to be listed on the ingredients list generically as a "spice" or "natural flavor."[23] Sesame-based ingredients may also appear on the ingredients list under an unfamiliar name because FDA regulations do not specifically require manufacturers to use the word "sesame" when listing sesame-derived ingredients (*e.g.*, "tahini" rather than "sesame seed paste" or "sesamolin" instead of "sesame seed extract").[24]

As noted above, sesame is also excluded from, among other things, the FDA's CPG on food allergen cross-contact and from the definition of "allergen" used in food safety regulations. As a result, food manufacturers often fail to include sesame when developing controls for addressing allergen cross-contact risks.[25]

The lack of clear and consistent labeling of sesame can cause extreme difficulty for consumers with sesame allergies, who must navigate a confusing food environment in which mistakes can have life-or-death consequences. Some consumers report spending numerous hours contacting

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[18] Warren C, Chadha A, Sicherer S, Jiang J, Gupta R. Prevalence and severity of sesame allergy in the United States. JAMA Network Open. 2019; 2(8): e199144.

[19] Ruchi S. Gupta *et al*., *The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States*, 142 Pediatrics 1 (Nov. 19, 2018); Ruchi S. Gupta *et al., Prevalence and Severity of Food Allergies Among US Adults*. 2 JAMA Netw Open e185630 (Jan. 4, 2019).

[20] Ruchi S. Gupta *et al*., *The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States*, 142 Pediatrics 1 (Nov. 19, 2018).

[21] Ruchi S. Gupta *et al*., *Prevalence and Severity of Food Allergies Among US Adults*, JAMA Network Open, Jan. 4, 2019, at 1, 6–7, tbl. 2–3.

[22] *Id.*; Ruchi S. Gupta *et al*., *The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States*, 142 Pediatrics 1, 6, tbl. 3 (Nov. 19, 2018).

[23] *See* 21 C.F.R. §§ 101.22(h)(1), 182.10.

[24] 21 C.F.R. § 101.4 (requiring that ingredients be declared by their "common or usual name," but not specifically requiring sesame derivatives include the term "sesame"); *see also* Petition at 5–6; December 2018 Letter at 6; CSPI, Seeds of Change: While Some Companies Lead the Way in Sesame Allergen Labeling, Large Gaps Remain (2018), FDA-2014-P-2035-0292, Ex. 1 at 20–25.

[25] FARRP, Comment Letter on FDA's Request for Information (posted Jan. 29, 2019), FDA-2018-N-3809-1903 (noting that 48 percent of manufactures surveyed by FARRP did not manage sesame as part of their allergen control plan).

food companies to seek clear information about sesame risks for different products, often to find that the information is not available even on request.[26]

## III. CSPI's 2014 Petition for Mandatory Sesame Labeling Has Broad Public Support

On November 18, 2014, CSPI and six allergy experts petitioned the FDA for a rule to protect consumers from undeclared sesame in products by requiring sesame to be labeled as an allergen in foods. Specifically, the Petition requested that the agency take the following four actions: (1) require sesame-based ingredients be labeled in a similar manner to the Big Eight, that is, be listed by the name "sesame" in the ingredient lists of all foods, preventing their being listed simply as "spices," "natural flavors," or with an unfamiliar name; (2) add sesame to the list of allergens in the CPG to address both labeling and control sesame cross contamination; (3) issue public educational materials concerning sesame and sesame-based ingredients directed at restaurants and food providers; and (4) modify the model Food Code to reflect allergic risks of sesame so that restaurant workers are aware of the risk.

The FDA accepted the Petition for filing[27] and posted it on December 2, 2014 on www.regulations.gov. The agency received 793 comments in connection with the Petition, according to www.regulations.gov. All 330 publicly available comments are supportive of the Petition. Most of the publicly available comments were submitted by individuals who suffer or have a family member who suffers from a sesame allergy. The FDA also received comments from allergy advocacy groups and allergists.[28]

Many of the commenters discussed their personal experiences and their difficulty, and anxiety while, navigating the food environment. The following are a few examples:

> A mother commented that her 18-month-old son "was in the ICU because of an anaphylactic reaction to sesame seed." She said, "[i]f I want to give him anything new to eat, I have to call the company who manufactures the food to confirm that there's no sesame. Some companies have told me that they 'can't disclose that information.' . . . . [S]houldn't we know what's in [our food]? Why are [manufacturers] allowed to hide it under 'spices' or 'natural flavoring?' Do you have any idea what it's like to live with this fear?"[29]
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> A "pediatrician and the parent of a child with life threatening peanut and sesame allergy," commented that she "has seen [her] child struggle with anaphylaxis to the tiniest bit of sesame and taken care of children hospitalized and who have died from food allergies." She explained that "[i]t is a fear no one can understand." She noted that she "spend[s] hours calling companies, researching because of how sesame can be hiding in natural flavors or spices." Noting the lack of consistent labeling of sesame compared to other allergens, she said that dealing with a sesame allergy "is a whole different world."[30]

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[26] CSPI, Seeds of Change: While Some Companies Lead the Way in Sesame Allergen Labeling, Large Gaps Remain (2018), FDA-2014-P-2035-0292, Ex. 1 at 20–25.
[27] *See* FDA, Acceptance Letter of Petition (Nov. 25, 2014), FDA-2014-P-2035-0002.
[28] *See, e.g.*, CSPI & AAFA, Comment Letter on Petition (Feb. 27, 2017), FDA-2014-P-2035-0034; Richard C. Loria, Allergy and Asthma Associates, P.C, Comment Letter on Petition (Sept. 29, 2015).
[29] *See* Jenny Gutman, Comment on Petition (posted July 17, 2017), FDA-2014-P-2035-0149.
[30] *See* Erika Abramson, Comment on Petition (posted Oct. 31, 2018), FDA-2014-P-2035-0310.

> A mother commented that her son had an anaphylactic reaction after she "purchased a bag of breadcrumbs . . . to coat some chicken." As with many products, "[t]he label on the breadcrumbs packaging did not contain any mention of the word sesame." However, when she "called the breadcrumb company the next day . . . [t]he representative [said] . . . they sometimes use bread coated with sesame seeds, so it was highly likely that sesame was in fact in the breadcrumbs I had purchased." She noted that she was "shocked" by the company's response. She implored the FDA "to make labeling for sesame a requirement in this country."[31]

Additionally, CSPI provided further support for the Petition. In September 2015, CSPI authored the report *Open Sesame*, which, among other things, demonstrated the "pervasive and dangerous lack of information about a life-threatening [sesame] risk for consumers."[32] On November 3, 2015, CSPI submitted that report along with other supportive materials to the FDA.[33]

On February 27, 2017, CSPI and the Asthma and Allergy Foundation of America, a prominent allergy advocacy organization, wrote a letter to the FDA urging the agency to take action on the Petition.[34] The letter informed the FDA of a then-recently released National Academies of Sciences, Engineering, and Medicine report that found, among other things, that "evidence of the allergy prevalence and reaction severity to sesame seeds may warrant their inclusion on the priority allergen list in the United States."[35]

In April 2018, CSPI authored a second report, *Seeds of Change*, that provided key updates to CSPI's 2015 report, *Open Sesame*, and documented the prevalence and severity of sesame allergies and the failure of companies to clearly label sesame containing products.[36] The report also surveyed 22 major food companies and found that among them 14 had shown leadership on sesame by declaring it as an allergen. Nevertheless, 8 of the surveyed companies failed to declare sesame as an allergen.

On April 16, 2018, a meeting organized by CSPI was held among FDA officials, two food allergy advocacy organizations, two prominent allergists, and children with sesame allergies and their parents. The participants at the meeting "spoke of the serious effects of sesame exposure and the difficulties of avoiding foods with sesame."[37] The FDA "indicated it would take into consideration the perspectives shared as it continues to evaluate the issue."[38]

On May 3, 2018, CSPI submitted the *Seeds of Change* report to the petition docket, along with other supportive materials, including a letter to the FDA from Senators Christopher Murphy,

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[31] *See* Dora Straus, Comment on Petition (posted Apr. 6, 2018), FDA-2014-P-2035-0251.
[32] *See* CSPI, Open Sesame: Why Sesame Must Be Disclosed as an Allergen on Food Labels 3 (2015), https://bit.ly/2QueLfy.
[33] CSPI, Comment Letter on Petition (Nov. 3, 2015), FDA-2014-P-2035-0019.
[34] *See* CSPI & AAFA, Comment Letter on Petition (Feb. 27, 2017), FDA-2014-P-2035-0034.
[35] *Id.*; *see also* National Academies of Sciences, Engineering, and Medicine, Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy 14 (2016).
[36] CSPI, Seeds of Change: While Some Companies Lead the Way in Sesame Allergen Labeling, Large Gaps Remain (2018), https://bit.ly/39yYUTD.
[37] FDA, Memorandum of Meeting on Petition (April 27, 2018), FDA-2014-P-2035-0296.
[38] *Id.*

Richard Blumenthal, Edward Markey, Sheldon Whitehouse, and Jack Reed.[39] The Senators said that "concerned parents and citizens deserve answers and action" and "urge[d] the FDA to take swift action to address the petitioners' request."[40]

To assist with evaluating the Petition, on October 30, 2018, the FDA published a request for "data and other information on the prevalence and severity of sesame allergies in the United States and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient."[41]

The comment period for the FDA's request for information closed on December 31, 2018.[42] The FDA received approximately 9,400 comments on its request for information, including 4,600 of which were submitted as a group by CSPI.[43] The overwhelming majority of the comments—many of which came from individuals who have been personally affected—were supportive of requiring manufacturers to clearly and transparently label sesame and of protecting consumers with sesame allergy.

CSPI also provided further support for its petition in the FDA's request for information. In particular, CSPI submitted a new prevalence and severity study conducted by Ruchi S. Gupta *et al.*[44]; joined nine allergy advocacy organizations in a comment supporting mandatory labeling; solicited and submitted 4,600 individual consumer comments in support of mandatory labeling; and sent a further supplemental comment.[45]

In addition, CSPI and another organization, the Asthma and Allergy Foundation of America (AAFA) gathered adverse event reports related to sesame using two online survey instruments that were circulated via social media and patient advocacy networks. As of December 30, 2018, CSPI had collected 357 adverse event reports, which it submitted by e-mail to the FDA's Adverse Event Reporting System (CAERS).[46] On December 12, 2018, AAFA submitted 225 adverse event reports to the CAERS.[47]

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[39] *See* CSPI, Comment Letter on Petition (May 3, 2018), FDA-2014-P-2035-0292.

[40] *See* Letter from Christopher Murphy, Richard Blumenthal, Edward Markey, Sheldon Whitehouse, & Jack Reed, Sen., to Scott Gottlieb, Comm'r, FDA (Mar. 20, 2018), FDA-2014-P-2035-0292, Ex. 2.

[41] *See* 83 Fed. Reg. 54,594; *see also* FDA, Sesame as an Allergen in Food (Dec. 31, 2018), FDA-2018-N-3809-0001.

[42] *Id.*

[43] Sesame as an Allergen in Food Docket, FDA-2018-N-3809; CSPI, Batch Comments on Petition (posted Feb. 1, 2019), FDA-2018-N-3809-2529, 32–34.

[44] Ruchi S. Gupta *et al.*, *The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States*, 142 Pediatrics 1, 5 & tbl. 2 (Nov. 19, 2018).

[45] *Id.*; AAFA *et al.*, Comment Letter on FDA's Request for Information (Dec. 21, 2018), FDA-2018-N-3809-2055; CSPI, Batch Comments on Petition (posted Feb. 1, 2019), FDA-2018-N-3809-2529, 32–34; December 2018 Letter.

[46] *Sesame Reporting Form*, CSPI, https://bit.ly/2XSBTsL; E-mail from Sarah Sorscher, Dep. Dir. Regulatory Affairs, CSPI, to Katherine Vierk *et al.*, Dir., Div. of Public Health Info. & Analytics, FDA (Dec. 30, 2018).

[47] The AAFA 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, 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. Email communication from Jenna Riemenschneider, Director of Advocacy and Special Projects, Asthma and Allergy Foundation of America, to Sarah Sorscher, Deputy Director of Regulatory Affairs, Center for Science in the Public Interest (February 11, 2021).

## IV. The FDA's Voluntary Guidance is Insufficient to Protect Consumers

Although more than six years have passed since CSPI filed the Petition, the FDA has neither granted nor denied the Petition, and it has not issued mandatory protections for consumers with sesame allergy.

Instead, in November 2020, the agency issued a draft guidance on voluntary labeling for sesame allergy. The draft guidance acknowledges the FDA's authority to require allergen labeling beyond the Big Eight listed in FALCPA, saying "if a new food allergen emerges, we can use our existing authorities to ensure appropriate labeling."[48] Specifically, the agency cited its authority to require that ingredients be declared by their common or usual name, as well as the authority conferred under FALCPA to require disclosure of allergens beyond the Big Eight when used as spices, flavorings, colorings, or incidental additives.

The agency also acknowledged the growing body of evidence on sesame allergy, including the 2017 report by the National Academies of Sciences, Engineering and Medicine, the publication by Gupta, *et al.*, of a nationwide survey conducted in 2015-16 documenting the prevalence and severity of sesame allergy among adults and children, as well as submission of adverse event reports by CSPI and others to the agency's CAERS database. The agency concluded that: "[b]ased on information received in the comments to the notice, the 2014 citizen petition (and comments submitted to the corresponding docket), other correspondence, as well as adverse event reports and recent publications with prevalence data, it appears that sesame allergy may be an increasing problem in the U.S. population."

Yet rather than acting on this information to require sesame to be declared on food labels, the agency indicated it would "continue to evaluate the emerging evidence" and that it was "working to develop factors to inform future regulatory actions related to sesame and other emerging food allergens, including possible labeling requirements." In the meantime, the agency stated it would "recommend . . . that manufacturers voluntarily take steps to help consumers who are allergic or sensitive to sesame by disclosing the presence of sesame in packaged foods, even in circumstances where such disclosure would not be required (e.g., in spices and flavorings)."

Such "recommendations" are insufficient to protect consumers with sesame allergy. As CSPI documented in its 2018 Seeds of Change report, many companies continue to lag behind in adopting sesame allergen labeling. These major food companies apparently were not persuaded to adopt sesame allergen labeling to avoiding life-threatening risks to their customers. There is little reason to believe that universal adoption of sesame labeling can be achieved by the FDA merely "recommending" the practice.

And universal adoption is critical. Without it, individuals considering whether to consume a food product have no way of knowing whether "sesame" is absent from the product's label because the food is free of sesame and therefore safe to eat, or if instead the manufacturer has simply neglected to identify it as an ingredient. In fact, a patch-work voluntary system could give consumers the false impression that they can rely on product labels to determine whether sesame is present, when, under the FDA's proposal, they can rely on no more than the good

[48] Food and Drug Administration. Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry. November 2020, https://www.fda.gov/media/143521/download.

grace of food manufacturers. This could lead to serious allergic reactions to products that consumers had erroneously assumed to be devoid of sesame.

Given the ample evidence now available documenting the risks of sesame allergy, the proposed draft voluntary guidance is simply an unnecessary digression on the path to mandatory labeling, contributing to additional delay after the agency has already lagged unreasonably in its response to CSPI's 2014 petition.

We therefore urge the agency to grant CSPI's petition, replacing the draft guidance with a proposed rule requiring mandatory sesame labeling.

Questions related to this comment can be directed to Sarah Sorscher, Deputy Director of Regulatory Affairs at Center for Science in the Public Interest, 202-777-8397, ssorscher@cspinet.org.

Sincerely,

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