



*Via Electronic Transmission*

February 25, 2021

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm 1061  
Rockville, MD 20852

**Re: Food and Drug Administration [Docket No. FDA-2020-D-0530] Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry, 85 Fed. Reg 71920 (November 12, 2020)**

To Whom it May Concern:

On behalf of the American Spice Trade Association (ASTA), we appreciate the opportunity to submit comments in response to the U.S. Food and Drug Administration's (FDA) *Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry*.

**Introduction**

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Our members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. We represent our members' U.S. interests by supporting regulatory compliance and maintaining relationships with U.S. agencies. ASTA shares FDA's commitment to food safety. Our highest priority is ensuring the supply of pure, safe spices to American consumers. Additionally, ASTA has consistently advocated to ensure that FDA is adequately resourced and are a member of the Alliance for a Stronger FDA.

ASTA has a long history of working with food regulatory authorities, including FDA, and we are pleased to provide the following comments in response to the FDA's proposed voluntary guidance on disclosure of sesame as an allergen. ASTA supports science-based policies pertaining to allergens and believes that decisions to identify major food allergens should be based strictly on the best available science. Many of ASTA's members import and process sesame seeds. If credible research identifies sesame as a major allergen in the United States, based on prevalence and severity data, ASTA supports the disclosure of sesame as an allergen on food labels.

ASTA is submitting comments on the *Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry* on three issues, and overall, ASTA would support either FDA revising or revoking the voluntary guidance for these reasons. One, within the spice and seasoning industry, it is already current practice to label sesame by its common or usual name and not include sesame in a general declaration of “spice(s).” This is based on long-standing FDA policy stating that sesame is not considered a spice. Two, the movement of two separate bills declaring sesame a major food allergen in the previous Congress via different versions of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, and the likely taking up of this issue again in the current Congress, could create conflict and confusion between the legislative process and the voluntary guidance if the draft voluntary guidance is not revoked. In the meantime, ASTA is supportive of FDA extending enforcement discretion to manufacturers who are working to label sesame transparently. Three, the FDA should not issue draft voluntary guidance on a food safety issue, as the guidance does not provide information on issues necessary for implementation, such as consistent allergen labeling and an implementation time frame. Given current industry practices for labeling of sesame, the developing legislative process to address sesame as a potential allergen, and the lack of information in the draft voluntary guidance, ASTA is concerned that the voluntary guidance creates significant confusion for industry. As such, ASTA is concerned about the precedent that this approach sets for potential future allergens. Instead, ASTA is supportive of a scientific assessment for future allergen considerations and would support the creation of a regulatory framework by the FDA to address allergen labeling guidance now and in the future.

#### **Current FDA Policy Already Provides that Sesame Should Not Be Labeled Under the Generic Declaration of Spices**

The FDA Compliance Policy Guide (CPG) Sec. 525.750 for Spices<sup>1</sup> currently defines spices as: “Aromatic vegetable substances, in the whole, broken, or ground form, whose significant function in food is seasoning rather than nutrition. They are true to name and from them no portion of any volatile oil or other flavoring principle has been removed.” The CPG goes on to state that sesame seeds “are not considered to be spices. When used as an ingredient in foods they should be declared on the label by common or usual name[.]” The practical implication of this existing FDA policy guide is that sesame seeds should already be labeled on food products, and not listed under “spices” on a label.

As stated above, the FDA definition for the term spices includes products in several forms, including ground. While following the CPG, ASTA interprets it such that the FDA does not consider sesame seeds to be a spice in any form. Therefore, ground sesame seeds should be labeled as sesame, even if the ground sesame seeds are added to a spice or seasoning mix. ASTA recognizes that there are some scenarios in which sesame may not be labeled as an ingredient, such as in flavors or other ingredients. As an example, sometimes sesame-based flavorings are used in seasoning blends. In these cases, the manufacturers would not be required to disclose the sesame ingredient. However, some manufacturers choose to voluntarily declare sesame as an allergen in order to provide more information to the consumer and appreciate the flexibility offered by the draft voluntary guidance to do so. In these cases, the manufacturers would appreciate the continued flexibility from the agency to label sesame as an allergen. It is noteworthy that this scenario arises from the presence of sesame in a flavoring ingredient, rather than a spice.

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<sup>1</sup> <https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074468.htm>

With respect to spices, ASTA was surprised that in the voluntary guidance, FDA indicated that sesame may be included under a generic declaration of spice without being specifically labeled. It is ASTA’s interpretation that the draft guidance on voluntary sesame labeling is inconsistent with the current FDA CPG policy, which states that sesame must be labeled and cannot be included in a general declaration of spice or in a seasoning blend. In the voluntary draft guidance, FDA recommends “that manufacturers, as a voluntary matter, clearly declare sesame in the ingredient list when it is used in foods as a “flavor” or “spice” in a parenthetical following the spice or flavor, such as, “spice (sesame),” “spices (including sesame).” It is current industry policy and practice that sesame included in a spice blend already be labeled with the term “sesame” in line with the current FDA CPG guidance.

A study by the Food Allergy Research and Resource Program (FAARP) confirms the ASTA interpretation and industry policy under the CPG. The FAARP document entitled Response to Docket No. FDA-2018-N-3809 Sesame as an Allergen in Foods, which was previously submitted to the FDA, surveyed consumer product companies and ingredient suppliers regarding sesame labeling. As shown on the chart below, located on page 8 of the document, no products were reported by ingredient manufacturers as Products with Undeclared Sesame in Spice:

<b>Ingredients</b>			
Total Number of Products Manufactured	42,249		
Products that Contain Sesame	1,139 -1,439	2.7-3.4%	
Products with Sesame Declared	939	2.2%	65%-82%
Products with Sesame Not Declared	30 -330	0.07-0.78%	3%-23%
Products with Sesame in Flavor	720	1.7%	50%
Products with Sesame in Spice	286	0.7%	20%
Products with Undeclared Sesame in Flavor	30		2.1%
Products with Undeclared Sesame in Spice			0%

Furthermore, the FAARP study included information on consumer products with “undeclared Sesame in Spice.” These finished food products accounted for only 4 of the 38,013 manufactured food products included in the survey, which amounts to only 0.01% of the total products with undeclared sesame in spices. ASTA would consider this minor percentage of products to be mislabeled and not in line with established industry guidance and practice.

ASTA has always interpreted the current FDA policy set out in the CPG, which has existed for 40 years, that sesame seeds, in any form, should be labeled by their common or usual name, and not under the general declaration as “spice(s).” It is with this interpretation of current FDA policy in mind that ASTA is concerned that the FDA voluntary draft guidance may confuse the current established industry policy that sesame should be labeled, and not included under the general label of spice(s) or in seasoning mixture as spices. Given that it is already currently industry practice that sesame would not be labeled under the generic declaration of “spice(s),” ASTA requests that if FDA does not revoke the voluntary draft guidance in its entirety, FDA at least remove “spices” from the voluntary guidance. In this case, ASTA would request that FDA clarify that sesame used in the manner of a spice, should always be labeled as sesame, and not as “spice(s).”

### **FDA Should Revoke the Voluntary Guidance Due to the Legislative Process and the FASTER Act**

During the 116<sup>th</sup> Congress, both houses of Congress pursued the designation of sesame as a major allergen through different legislative versions of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2020. Both bills would have identified sesame as the ninth major food allergen and subject it to the same labeling requirements that apply to other major food allergens under the Food Allergen Labeling and Consumer Protection Act (FALCPA). The application of FALCPA to sesame would ensure national uniformity and consistency in the labeling of major food allergens, allow for the efficient use of industry resources to support long-term instead of short-term labeling changes, and make it easier for those with allergies to avoid specific foods. It is expected that the FASTER Act will be reintroduced quickly in the current Congress. Due to the passage of the previous legislation unanimously by both houses of Congress, as well as food industry support for legislative action on this issue, ASTA would support the revocation of the current voluntary draft guidance if and when Congress passes legislation. This path would provide clarity for industry on a path forward and provide a consistent regulatory framework for labeling sesame as a major food allergen under FALCPA. In the meantime, ASTA supports enforcement discretion for the disclosure of sesame as an allergen, even when not strictly in adherence to the practices outlined in the guidance. For example, if manufacturers label sesame in the “contains” or ingredient statement.

### **Voluntary Guidance Should Not Address Food Safety Issues like Allergens**

Allergens are a food safety issue, and ASTA takes allergens, allergen labeling, and food safety very seriously. The voluntary approach to sesame is inconsistent with the manner in which FDA has handled other allergens. Allergen labeling is required under FALCPA, which specifies the major food allergens and does not currently list sesame. FALCPA expressly provides that FDA may require disclosure of a nonmajor allergen found in spice or flavoring, but only if it does so through rulemaking.<sup>2</sup> Additionally, as part of the Food Safety Modernization Act (FSMA) Preventive Control regulations, companies are required as part of a food safety plan to have preventive controls for allergens in place. Furthermore, FDA has previously required labeling of other foods that are sensitizers, such as sulfites<sup>3</sup> and carmine/cochineal extract<sup>4</sup>, via regulation. A food is considered mislabeled if the sulfite information does not correctly appear on the finished product label, and the mislabeled food is subject to a recall.

ASTA is not supportive of using voluntary guidance to address a food safety issue such as an allergen. ASTA is concerned that the FDA’s voluntary approach to sesame labeling as an allergen is potentially confusing and problematic, especially considering that the voluntary guidance does not provide information that is necessary for supporting consistent labeling of allergens. For example, FDA did not provide a timeline for the implementation of sesame labeling in the voluntary draft guidance. The lack of clarity on an official implementation date will likely result in inconsistent compliance from one manufacturer to another, which will in turn result in a lack of clarity on allergen labeling for consumers. The guidance also recommends declaration of sesame within the ingredient statement, which will create a discrepancy for products labeled with a “contains” allergen statement, as this statement will not list sesame and could cause consumers to assume the product does not contain sesame. The voluntary guidance on sesame creates potential for confusion and inconsistency for both manufacturers and consumers.

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<sup>2</sup> 21 U.S.C. 343(x).

<sup>3</sup> 21 CFR 130.9.

<sup>4</sup> 21 CFR 73.100(d)(2).

ASTA would like any future allergen labeling guidelines to be clear and consistent, and based on science-based policy set forth by FDA. Rather than providing a standalone voluntary guidance for the declaration of sesame, we urge FDA to develop a science-based regulatory framework to evaluate whether additional ingredients should be disclosed as food allergens based on prevalence, severity, and potency of the potential allergen. This would allow FDA to have a process in place to evaluate potential allergens and implement clear and consistent policies and guidance regarding the declaration and management of allergens, which will better serve consumers.

### **Conclusion**

ASTA appreciates the opportunity to submit comments to the FDA on the *Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry*. In conclusion, ASTA is supportive of efforts to provide consumers with relevant information about allergens and supports the labeling of sesame if it is determined to be an allergen. However, the approach outlined in the voluntary draft guidance raises significant questions and concerns. As such, ASTA requests that FDA revise or revoke the voluntary draft guidance because the spice industry already labels sesame by its common or usual name, pending legislation may create confusion with the guidance on voluntary labeling, and ASTA does not support the use of voluntary guidance to address food safety concerns. Additionally, while the industry transitions to sesame labeling, FDA should practice enforcement discretion for the disclosure of sesame even when not strictly in accordance to the approach outlined in the guidance. Furthermore, ASTA believes the voluntary approach towards sesame labeling sets a concerning precedent for the future of allergen management. Instead, ASTA would support FDA creating a regulatory framework to evaluate future potential allergens that is clear, consistent, and scientifically based.

Please feel free to reach out to ASTA with any questions or follow up.

Sincerely,

A handwritten signature in black ink, appearing to read "Laura Shumow", with a long horizontal flourish extending to the right.

Laura Shumow  
Executive Director  
American Spice Trade Association