February 25, 2021

Submitted electronically via regulations.gov

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

Re: Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; Docket No. FDA-2020-D-0530 (November 12, 2020)

The undersigned organizations appreciate the opportunity to provide comments to the U.S. Food and Drug Administration (FDA or agency) regarding its draft guidance titled *Voluntary Disclosure of Sesame as an Allergen* (draft guidance) and looks forward to supporting the agency's 2021 commitment to *Step Up Efforts to Protect Consumers with Food Allergies*[1]. Manufacturers and suppliers across the supply chain continue to work to be responsible players regarding the labeling of food allergens. We support the goal of providing consumers with food allergies with critical information about the presence of sesame in products. We recognize that the draft guidance is considered a first step while FDA explores actions for future food allergens "beyond the major eight," and we hope to work with the agency to ensure consistent requirements for this important public health issue.

Support Legislative Efforts to Make Sesame a Mandatory Allergen

We believe a uniform approach to the labeling of sesame will benefit consumers and manufacturers. The undersigned support the Food Allergy Safety, Treatment, Education and Research (FASTER) Act, previously introduced to the 116th Congress and specifically the version passed by unanimous consent in the Senate[2]. This version of the FASTER Act would identify 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). Not only would this provide certainty for manufacturers and ensure national uniformity and labeling consistency across the United States, but consumers would then have assurance that sesame is treated like other allergens throughout the supply chain. We aware that a bipartisan version of the FASTER Act, the FASTER Act of 2021[3], is moving forward in the 117th Congress and look forward to working with the current Congress on this legislation.

We are concerned that differences between the approach and application of the FASTER Act and FDA's draft guidance, if finalized, could be both confusing to consumers and costly to manufacturers due to the potential need for multiple labeling changes. We therefore encourage FDA to take every measure possible to prioritize support for Congressional efforts to enact the FASTER Act and ensure consistency between these efforts and any labeling guidance related to sesame.

---

[1] https://www.fda.gov/news-events/fda-voices/fda-steps-efforts-protect-consumers-food-allergens
[2] https://www.congress.gov/bill/116th-congress/senate-bill/3451/text
[3] https://www.congress.gov/bill/117th-congress/house-bill/1202?s=1&r=8

Support Rulemaking over Voluntary Guidance for Sesame Labeling

While we appreciate FDA's first steps in the process to address concerns around the labeling of sesame when used as a spice or flavor, the undersigned believe it would be most appropriate to address this issue through notice-and-comment rulemaking rather than voluntary guidance. This process allows an opportunity for meaningful stakeholder engagement and solicitation of critically important data and information. Once finalized, a rule would establish mandatory, enforceable requirements, consistency in industry and consumer expectations, and a clear timeline for implementation. Without this process, manufacturers and suppliers [represented by the undersigned organizations] have concerns with the voluntary guidance approach, including, but not limited to, the following:

- **Federal Preemption:** The labeling recommended in the draft guidance is not subject to federal preemption and the accompanying national uniformity, which could potentially result in the implementation of inconsistent labeling approaches across the country;
- **Timeline for Implementation:** The lack of a defined timeline for the implementation of the draft guidance could result in inconsistent application from manufacturer to manufacturer;
- **Obtaining Appropriate Information:** Due to the potential for inconsistent implementation, there will likely be challenges in obtaining consistent supplier and manufacturer information between businesses across the supply chain;
- **Supply Chain Impacts:** The voluntary approach for addressing sesame labeling has implications for the supply chain, manufacturing sites, regulatory inspections, and potential to require multiple labeling changes. These impacts are best assessed via analysis procedures that accompany notice-and-comment rulemaking;
- **Certainty and Consumer Understanding:** Most importantly, the draft guidance's approach may be confusing to consumers. It could result in labeling inconsistencies, where consumers cannot be assured that sesame, if present will be declared, and that if it is declared, it will not be declared in the "Contains" statement with other allergens.

We stand ready to work with FDA to discuss a solution to both address manufacturers concerns and ensure that it is easy for those with allergies to avoid specific foods.

Support a Clear Regulatory Process and Framework for Identifying New Allergens

The undersigned appreciate and strongly support FDA developing factors or scientific criteria for identifying and determining new food allergens beyond those in the FALCPA and look forward to engaging in this process. As FDA noted in the draft guidance, countries around the world have built similar frameworks, using data to determine what would be considered a "priority allergen." Many are built on criteria for risk assessment that includes data on allergy prevalence in that population, severity, and potency of a potential allergen. Building out these criteria and establishing a strong science-based framework is essential so that we can better understand and prepare for potential future changes to FALCPA.

In the proposed draft guidance, FDA specifically referenced "data gap in national prevalence data derived from clinically-based diagnosis of sesame allergy." As FDA builds criteria to determine changes to the list of FDA's list of major food allergens, we encourage the agency to dedicate resources to address these gaps in data, the structure for reporting adverse events, and pursue a process that engages feedback from a wide variety of stakeholders. We encourage FDA to not only work with the food and beverage industry, but specifically look

toward experts in the food allergen space like Food Allergy Research & Education (FARE), Food Allergy Research and Resource Program (FAARP), and the Asthma and Allergy Foundation of America (AAFA) to inform this work. By developing scientific standards that are agreed to by a range of stakeholders from the food and beverage industry to non-governmental organizations, we can establish a clear and consistent, science-based process for determining future food allergens that require additional controls such as mandatory allergen labeling.

The undersigned appreciate FDA's important work and thanks the agency for the opportunity to comment on this draft guidance. We look forward to partnering with FDA on science-based policies and frameworks that provide clarity and certainty to manufacturers and consumers.

Should you have any questions about this letter, please contact Jessica Hixson [jhixson@snacintl.org, 703.836.4500 ext. 205].

Sincerely,

American Bakers Association
American Frozen Food Institute
American Spice Trade Association
Consumer Brands Association
FMI-The Food Industry Association
International Dairy Foods Association
Juice Products Association
National Fisheries Institute
National Grocers Association
SNAC International
The Association for Dressings & Sauces
The National Seasoning Manufacturers Association