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Re: Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; Docket No. FDA-2020-D-0530 (November 12, 2020)

SNAC International appreciates the opportunity to provide comments to the U.S. Food and Drug Administration (FDA or Agency) regarding its draft guidance titled *Voluntary Disclosure of Sesame as an Allergen* and looks forward to supporting the Agency's 2021 commitment to *Step Up Efforts to Protect Consumers with Food Allergies*[1]. Founded in 1937, SNAC International and its member companies continue to work to be responsible players regarding the labeling of allergens. We support the goal of providing the food allergy consumer with critical information about sesame in products. We recognize that the draft guidance is considered a first step while FDA explores "other potential actions to protect consumers who may have allergies to sesame or other food allergens beyond the major eight." We hope to work with the Agency to bring more clarity and consistency to recommendations and requirements related to this important public health issue. We recommend that future actions by the agency include notice-and-comment rulemaking to address sesame labeling (unless this would be moot due to future legislative action), and to establish science-based criteria to assess food allergens.

SNAC Supports Legislative Efforts to Make Sesame a Mandatory Allergen

SNAC believes that a uniform approach to the labeling of sesame will benefit consumers and manufacturers. SNAC supports 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 and clearly labeled in the same fashion. SNAC is aware that a bipartisan version of the FASTER Act,

[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

the FASTER Act of 2021[3], is moving forward in the 117th Congress and looks forward to working with the current Congress on this legislation.

SNAC members, however, 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. For example, if a company were to voluntarily comply with FDA's draft interim guidance today by modifying its labels to declare sesame within the ingredient statement and then the FASTER Act subsequently passes, that same company would have to relabel to comply with the FASTER Act by declaring sesame in the "Contains" statement. SNAC therefore encourages FDA to take every measure possible to prioritize support for Congressional efforts to enact the FASTER Act and ensure consistency between that legislative effort and any labeling guidance related to sesame. For example, if/when the FASTER Act, or similar legislation is signed into law, SNAC encourages FDA to withdraw this draft voluntary guidance for the sake of consistency. In the absence of federal legislation, SNAC supports FDA establishing, through notice and comment rulemaking, science-based criteria to evaluate allergens determine which allergens have the prevalence and severity to merit mandatory disclosure

SNAC Supports 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, SNAC believes it would be most appropriate to address this issue through notice-and-comment rulemaking rather than voluntary guidance. SNAC believes that agencies best follow the Administrative Procedure Act (APA) when proceeding through notice-and-comment rulemaking in circumstances when the agency is establishing a new regulatory standard[4], including when that standard is styled as guidance. Because the draft guidance would create a new regulatory norm with respect to sesame labeling, it is a substantive rule that should be issued via notice-and-comment rulemaking. The notice-and-comment rulemaking 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 going through this process, manufacturers and suppliers 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 presented by the draft guidance, 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 label changes. These impacts are best assessed analysis procedures that accompany notice-and-comment rulemaking;

[3] https://www.congress.gov/bill/117th-congress/house-bill/1202?s=1&r=8

[4] 5 U.S.C. § 553.

- **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.

Given the public health importance of food allergen labeling, SNAC stands ready to work with FDA to discuss a solution to both address manufacturers concerns and ensure that it is easy for consumers with food allergies to easily identify the foods they should avoid.

SNAC Supports a Clear Regulatory Process and Framework for Identifying New Allergens

SNAC appreciates and strongly supports FDA developing factors or scientific criteria for evaluating food allergens beyond those identified as major food allergens under FALCPA and looks forward to engaging in this process. We urge FDA to prioritize creating a scientific assessment standard that can be applied to all food allergens to assess whether their prevalence and severity of reaction warrant mandatory disclosure. Having a consistent science-based standard that reflects input from all stakeholders will benefit the food-allergic community because it will ensure we are not over- or under-declaring allergens. Defining criteria via rulemaking is essential so that we can better understand and prepare for potential future allergen-related labeling changes.

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, potency, and are modeled off (or include) reference doses when appropriate. Additional considerations for this approach were outlined in SNAC's comments from FDA's 2018 Request for Information on the Labeling of Sesame in Foods, in which, we note the importance of establishing threshold levels for all current or future food allergens. Establishing thresholds will help address challenges with the implementation of FSMA by specifically identifying levels below which it is unlikely a food allergic individual would experience an adverse effect.

In the proposed draft guidance, FDA specifically referenced a "data gap in national prevalence data derived from clinically-based diagnosis of sesame allergy". As FDA builds criteria to determine changes 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. SNAC encourages FDA to not only work with 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.

SNAC appreciates the opportunity to comment on FDA's draft guidance. We look forward to partnering with FDA moving forward 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 our team.

Thank you for your consideration of these comments.

Elizabeth Avery
President & CEO
SNAC International
703.836.4500 ext. 204
1560 Wilson Blvd, Suite 440, Arlington, VA 22209
www.snacintl.org