Asthma and Allergy Foundation of America

May 23, 2024

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

Submitted via regulations.gov

**Re: Docket No. FDA–2016–D–2343, Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry; Chapter 11: Food Allergen Program**

To Whom It May Concern:

On behalf of AAFA, the Asthma and Allergy Foundation of America, thank you for the opportunity to offer comments on FDA's draft guidance to manufacturers, specifically with regard to Chapter 11, Food Allergy Programs. AAFA is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. We are dedicated to improving the quality of life for people with allergic diseases and asthma through education, advocacy and research.

Overall, AAFA is encouraged that the Chapter offers very detailed guidance to manufacturers regarding manufacturing practices, labeling practices, assessment of allergens in the supply chain, and other allergen program components. We appreciate the FDA's ongoing attention to allergen control and the level of detail and attention paid to the importance of food allergens.

We believe that FDA should take two further key steps, whether through this Chapter or in additional policies and guidance: to address manufacturers' stated concerns about allergen control for sesame, and to advance policy development regarding evidence-based thresholds for both allergen control

programs and precautionary labeling. Our recommendations are detailed below.

**Specific guidance with regard to allergen control for sesame**

As AAFA has detailed in multiple comments to, and meetings with, FDA, some manufacturers responded to new labeling requirements for sesame effective in 2023 by adding sesame as an ingredient to products that previously did not contain them. In addition, precautionary allergen labels such as "may contain" warnings for sesame have proliferated on other products, with no clarity on whether manufacturers have taken meaningful steps to try to reduce the risk of cross contact.

Given that manufacturers have been claiming that sesame poses unique challenges for baking, AAFA believes more work must be done to help manufacturers navigate those challenges. *Chapter 11 must include an additional example that is specific to sesame.* The draft Chapter reflects an important opportunity for FDA to delineate precisely how manufacturers of products containing sesame can establish meaningful allergen control policies that are reflective of the specific concerns that this ingredient may raise in the manufacturing process. We strongly urge FDA to add such examples, either in this draft Chapter or in separate guidance.

**Evidence-based standards for manufacturing and for precautionary labeling**

AAFA also appreciates that FDA reiterates in this guidance that precautionary statements should not take the place of good manufacturing practices. FDA has been reminding manufacturers of this principle since at least 1996, unfortunately, without clear shifts in manufacturer behavior. This Chapter 11 Draft Guidance offers direction to manufacturers who act in good faith to reduce the risk of allergen exposure, but provides insufficient guidance to change the behavior of manufacturers who are prioritizing cost savings,

avoidance of a recall, or reduction of legal liability rather than safety for consumers.

The heart of the problem is that FDA provides no current, consistent, nor mandatory policy on precautionary allergen labels. Manufacturers are free to use such labels or not, and are not guided by any particular evidence standard.

This puts consumers in a lose-lose position: precautionary allergen labels do not warn people when a meaningful allergy risk is present; and in other cases, such labels may also unnecessarily restrict food options for people with food allergies when these labels are added to a product that does not in fact contain unsafe levels of allergen(s). The proliferation of precautionary labels for sesame is just one example of a broader pattern of inconsistent and haphazard labels across all food allergens.

**AAFA supports evidence-based food allergen policies that are rooted in data on the established allergen threshold doses that are likely to trigger allergic reactions in specific proportions of consumers.** There is a large and growing body of evidence for many top allergens regarding the thresholds under which the vast majority of patients with food allergies will not react to upon exposure. The best evidence on actual risk levels can potentially inform both allergy control programs and labeling policies.

We were encouraged to see that FDA notes in several parts of Chapter 11 that "published data on population threshold dose responses to various food allergens are becoming increasingly available." FDA also notes that threshold data could be used to inform allergen control programs (in both 11.3 Understand the Hazard Requiring a Preventive Control; and 11.8.3.2 Determining the appropriate supplier approval and verification activities). However, pointing manufacturers toward the option of using this data is both burdensome and unrealistic, and would likely lead to inconsistent results at best.

We therefore urge FDA to remove threshold-based approaches from the guidance to individual manufacturers and to begin the process of assessing threshold-based standards for developing evidence-based, mandatory and consistent standards for precautionary labeling as well as for allergen control programs. The role of analyzing the current science on threshold levels, and translating that science into meaningful policy, should belong to the FDA.

Thank you very much for your time and attention. AAFA looks forward to continuing to work with the FDA to identify meaningful, evidence-based solutions to guide manufacturing and labeling processes. In light of FDA's broader support of innovation in the food allergy sphere, including CDER's recent review and approval of Xolair for food allergies, this is a pivotal time for the agency to move science and policy forward for people with food allergies, and we look forward to continuing to work together.

If you have any questions, please do not hesitate to contact me at kmendez@aafa.org.

Sincerely,

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