



May 28, 2020

Updated with additional signatories: June 1, 2020

Dr. Susan Mayne
Director, Center for Food Safety and Applied Nutrition
Food and Drug Administration (FDA)
5001 Campus Drive
College Park, MD 20740

Re: FDA-2020-D-1139 Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines Guidance for Industry

Dear Dr. Mayne,

We are commenting today on behalf of the undersigned organizations regarding FDA’s recent guidance relaxing certain food labeling requirements for industry in the context of the COVID epidemic. We acknowledge that the unprecedented pandemic may require manufacturers to make minor formulation changes due to lack of available ingredients. As discussed below, we appreciate FDA’s recognition of the breadth of foods that can cause safety concerns, and request that FDA require manufacturers to disclose all substitutions on their websites to create transparency for consumers.

We strongly appreciate FDA’s noting of the range of foods that can trigger allergic reactions, which expands beyond those initially codified in the Food Allergy Labeling and Consumer Protection Act. The guidance states:

In addition to the eight major food allergens defined at section 201(qq) of the FD&C Act, several other foods (such as sesame, celery, lupin, buckwheat, molluscan shellfish, and mustard) are recognized as priority allergens in other parts of the world, including Canada, European countries, and Japan. There are also other ingredients (such as glutamates and sulfites) that can cause adverse reactions. Manufacturers should avoid substitutions that could result in a safety concern without making a conforming label change or providing other means to inform consumers of the change.

As we have discussed with FDA through our work supporting the agency's steps toward sesame labeling^{1,2}, foods that are not in the "top eight" can still trigger serious, life-threatening allergic reactions.

In synthesizing the feedback we have received in the past few days since this guidance was posted, we would like to request one minor modification regarding this guidance to create transparency and allow food allergic consumers to confirm if a product is still "safe." To that end, we recommend that the FDA require a manufacturer that makes *any* substitution to simply put a statement detailing the change in ingredient(s) on their website, including date and lot information, and to use their social media to help disseminate this message. The notice on the website can be discovered by current RSS feeds, which will further help with the dissemination.

While ingredients that raise safety concerns are our highest concern, we know that leaving that determination to manufacturers would result in an unreliable patchwork of notifications. By requiring *all* substitutions to be posted publicly, FDA will ensure that patients navigating less common allergies can identify changes, instead of permitting each manufacturer to determine which changes pose safety concerns. With this step, the advocacy community could potentially help compile a database that could serve as a resource to help food allergy families.

We note that this website and social media disclosure requirement would not need to apply to all modifications under the guidance – for example, *omissions* would not raise allergy or other safety concerns.

Again, we recognize both the dire situation prompting this temporary guidance, as well as the FDA's effort to include language specific to food allergy, including the top eight as well as sesame and other increasingly prevalent allergies. With a clear requirement that *all* substitutions be posted publicly, we feel confident that the risk to the consumer can be minimized to no more than baseline.

Thank you very much for your efforts. We look forward to a follow up conversation on this guidance. Additionally, when the current COVID crisis abates, we look forward to working with FDA to continue to advance permanent labeling requirements for sesame, and to promote the health and safety of all consumers with food allergies.

Sincerely,

Asthma and Allergy Foundation of America
Allergy Advocacy Association
Allergy & Asthma Network
AllergyStrong
American Partnership for Eosinophilic Disorders (APFED)
Center for Science in the Public Interest
CURED Nfp
E.A.T (End Allergies Together, Inc.)
Elijah-Alavi Foundation

¹ [AAFA Sends Letter to FDA Requesting Sesame Labeling Discussion](#), December 18, 2019.

² [AAFA Signs Letter Supporting Regulations to Label for Sesame](#), December 21, 2018.

Eosinophilic Family Coalition
Food Allergy & Anaphylaxis Awareness Connection Team (FAACT)
Food Equality Initiative
International FPIES Association
The Mastocytosis Society Inc.

CC: Dayle Cristinzio
Director, Stakeholder Engagement
Office of External Affairs
U.S. Food and Drug Administration