June 3, 2020

Susan Mayne, PhD
Director, CFSAN
5001 Campus Drive
College Park, MD 20740-3835

Re: Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines – Guidance for Industry, FDA Doc. No. 2020-D-1139-0009 (the "Temporary Guidance")

Dear Dr. Mayne:

The undersigned organizations share the mission of ensuring the safety of foods made available under the FDA's Gluten-Free Labeling Rule, 21 CFR § 101.91. The gluten-free community includes patients with celiac disease who must adhere to a strict gluten-free diet as the *only* treatment for celiac disease.

We are deeply concerned that the Temporary Guidance could (1) put consumers at risk who must adhere to a gluten-free diet and (2) confuse manufacturers concerning how to proceed under the Gluten Free Labeling Rule. Therefore, on behalf of consumers who must adhere to a strict gluten-free diet at all times, and especially during a pandemic, we urge the FDA to make a minor modification to the Temporary Guidance to include a specific reference to the Gluten Free Labeling Rule that clarifies how manufacturers should proceed in making substitutions involving gluten.

The Temporary Guidance states that the "FDA does not intend to object to the food industry making certain temporary and minor formulation changes without making conforming label changes when there are supply disruptions or an ingredient shortage exists as a result of the COVID-19 pandemic. For purposes of this guidance, minor formulation changes should be consistent with general factors [listed in the document]." *Temporary Guidance at p. 7*. While the document's "general factors" mention gluten in passing under the "SAFETY" factor, the term goes undefined, no reference is made to the Gluten Free Labeling Rule, and the factors are framed in permissive terms ("*should* be consistent").

Indeed, the Temporary Guidance's "general factors" are cast so vaguely, and the "temporary flexibility" suggested so nonspecific, that such substitutions involving gluten are likely, thus putting the communities we protect at great risk.

For example, a manufacturer who does not label its product "gluten free" but the label lists *only* ingredients that appear free of gluten may inadvertently substitute an ingredient with a gluten-containing grain (*e.g.,* substituting malt syrup for corn syrup) during this temporary timeframe. Though inadvertent, a substitution with gluten is extremely dangerous to patients with celiac disease because many consumers, out of necessity, purchase products not labeled "gluten free" if the ingredients listed appear safe. The Temporary Guidance should be modified to eliminate the risk of this outcome.

Likewise, a manufacturer relying on the Temporary Guidance as framed could substitute an ingredient in the reformulation of an existing product labeled "gluten free" while inadvertently introducing gluten into its product. This could likely occur if a manufacturer using oats from a reliable gluten-free source and properly labeling the product gluten-free under the Gluten Free Labeling Rule substitutes that ingredient with conventional oats, which carry significant risk of cross-contact. That substitution could introduce gluten into the product, possibly resulting in 20 parts per million of gluten or greater in that product, which would be noncompliant with the Gluten Free Labeling Rule and put consumers at risk. The Temporary Guidance introduces ambiguity into whether that substitution is an acceptable practice during the pandemic. It is not acceptable and is unsafe for those on a medically-prescribed gluten-free diet.

To ensure safe substitutions during the pandemic for patients restricted to a gluten-free diet, we request a minor modification to the Temporary Guidance by adding language to the end of Section C.2.a (Avoidance Considerations), as follows:

> 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. In addition, labeling of gluten-free foods is regulated under 21 CFR § 101.91, and manufacturers shall not make ingredient substitutions that result in a violation of 21 CFR § 101.91 (Gluten free labeling of food).[FN]
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> [FN]. Section 101.91(a): Definitions: (1) The term "gluten-containing grain" means any one of the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye): (i) Wheat, including any species belonging to the genus *Triticum;* (ii) Rye, including any species belonging to the genus *Secale;* or (iii) Barley, including any species belonging to the genus *Hordeum.* (2) The term "gluten" means the proteins that naturally occur in a gluten containing grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins). The term applies to malt, malt syrup, malt extract, yeast extract (from spent brewer's yeast) and smoke flavoring (when barley malt flour is a carrier agent).

In addition, we agree with the comments submitted on May 28, 2020 by numerous organizations that the FDA modify the Temporary Guidance to require manufacturers to disclose all substitutions on their websites to create transparency for consumers.[1]

We thank the FDA for considering our request to modify the Temporary Guidance to clarify its effect on the Gluten Free Labeling Rule and applaud the FDA for its recent work to ensure that foods mislabeled under the Gluten Free Labeling Rule are promptly taken off of store shelves to protect the public. We also encourage the FDA to push forward with its rulemaking efforts to provide clearer guidelines regarding the labeling of foods containing fermented or hydrolyzed ingredients, which the agency acknowledges "are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to . . . foods labeled as 'gluten-free.'" Proposed Rule, 80 Fed. Reg. 71990 (Nov. 18, 2015). So too here. If manufacturers rely on the Temporary Guidance as worded—without an express reminder from the FDA in that Guidance that their substitutions may not introduce gluten-containing ingredients into their products in violation of the Gluten Free Labeling Rule—the progress the FDA has made in recent years on behalf of celiac disease patients will be lost.

We urge the FDA to include the requested minor modification to clarify for manufacturers how to proceed when it comes to substitutions involving gluten.

Sincerely,

Gluten Free Watchdog
Beyond Celiac
Gluten Intolerance Group
National Celiac Association
Celiac Community Foundation of Northern CA
Dietitians in Gluten & Gastrointestinal Disorders
Society for the Study of Celiac Disease

cc:
Hon. Alex Azar, U.S. Health and Human Services Commissioner
Stephen M. Hahn, MD, U.S. Food and Drug Association Commissioner
Dayle Cristinzio, Director, FDA Stakeholder Engagement Office of External Affairs
Lynn Szybist, Supervisory Consumer Safety Officer, CFSAN

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