



June 16, 2020

Tricia Thompson, MS, RD  
Founder  
Gluten Free Watchdog

Dear Ms. Thompson:

Thank you for your letter of June 3, 2020, regarding the Food and Drug Administration's (FDA or we) guidance for industry entitled "Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines"<sup>1</sup> (COVID-19 Food Labeling Flexibility Guidance). Specifically, you asked FDA to update the guidance to include a reference to our Gluten Free Labeling Rule.

We received many comments on the COVID-19 Food Labeling Flexibility Guidance, and we take each concern, such as the ones you raise, seriously. We want to reiterate that FDA's temporary policy does not provide labeling flexibilities to industry if a health or safety issue would result, including the substitution of an ingredient containing gluten for a gluten-free ingredient.

We met with the Food and Beverage Issue Alliance (FBIA) on May 27, 2020, to share the concerns we are hearing from the allergen community regarding the COVID-19 Food Labeling Flexibility Guidance. Subsequently, FBIA issued a statement<sup>2</sup> on May 28, 2020, stating their commitment to utilizing the flexibilities provided in the guidance only in rare situations and communicating to consumers any substitutions that may be made.

The COVID-19 pandemic is causing some supply chain disruptions and ingredient shortages. Due to these disruptions and to ensure continued food production, the food industry requested flexibility when manufacturers need to make minor formulation changes that may cause the finished food label to be incorrect, but that do not pose a health or safety issue and do not cause significant changes in the finished product. The food industry advised FDA that they are currently unable to make conforming label changes to reflect these temporary formulation changes without slowing down the flow of production and distribution of some foods. FDA's temporary policy provides industry limited flexibilities under certain circumstances during the COVID-19 pandemic to help minimize the impact of the supply chain disruptions or ingredient shortages on food product availability. Because FDA is responsible for protecting the public health by ensuring the safety of our nation's food supply, we directly state in the COVID-19 Food Labeling Flexibility Guidance that such flexibilities are not to be used when they may pose

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<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-certain-food-labeling-requirements-during-covid-19-public-health>

<sup>2</sup> <https://static1.squarespace.com/static/5e7d1107dac60a6b3e3f098d/t/5ed0431531c1a80efe243d6f/1590706966867/FBIA+Statement+on+Ingredient+Flexibility+5.28.20.pdf>

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a health or safety issue. This would include the introduction of an ingredient containing gluten. Substitutions, in any amount, are not appropriate without a corresponding label change when the substituted ingredient is one that may cause a safety concern.

For transparency and consumer awareness, we continue to strongly encourage manufacturers to comply with labeling requirements and continue to make conforming labeling changes when they need to make formulation changes due to unforeseen supply chain disruptions or shortages brought on by COVID-19. We recommend manufacturers use alternative ways to communicate to consumers any formulation changes that are not reflected on the product label, which FBIA committed to doing in their statement as mentioned above.

We assure you that it is FDA's priority to protect consumers while also working to ensure a safe, secure, and adequate food supply during this public health emergency.

As you noted, we published a proposed rule entitled Food Labeling: Gluten-Free Labeling of Fermented or Hydrolyzed Foods (80 FR 71990, November 18, 2015). The additional requirements of a final rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to "gluten free" labeling of fermented or hydrolyzed foods. As of February 10, 2020, the final rule is under review at the Office of Management and Budget.<sup>3</sup> Issuing this final rule remains a top priority for FDA.

Thank you again for contacting us about this important matter. Please let us know if you have further questions or concerns.

Sincerely,



Susan T. Mayne, Ph.D., F.A.C.E.  
Director  
Center for Food Safety  
and Applied Nutrition

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<sup>3</sup> <https://www.reginfo.gov/public/do/eoDetails?rrid=130090>