August 12, 2022

Comments submitted by Beyond Celiac
In response to Docket Number FDA-2021-N-0553-0005
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Food and Drug Administration,

Beyond Celiac is a patient advocacy organization dedicated to finding new treatments and a cure for celiac disease, while also improving the lives of those currently living with celiac disease. Unfortunately, the only existing treatment for celiac disease is a strict, lifelong gluten-free diet. Gluten is found in wheat, which is one of the top 9 allergens and, therefore, reliably labeled under the Food Allergen Labeling and Consumer Protection Act (FALCPA). Gluten is also found in barley and rye, which are not top 9 allergens and therefore not called out on labels.

Unlike other conditions where there are options to manage inadvertent exposure, those with celiac disease must rely solely on accurate and complete food labels to maintain their health.

Given that the labeling laws written and enforced by the FDA are some of the only protections for those with celiac disease in the United States, Beyond Celiac firmly opposes the draft guidance Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Stakeholders (Docket Number FDA-2021-N-0553-0005). The guidance states that the FDA will not consider any petitions to add additional allergens under FALCPA, including gluten-containing grains, unless the allergen is proven to cause acute and life-threatening immune response. Beyond Celiac objects to this approach as it is detrimental to the gluten-free community.

One might argue that consumers with celiac disease are already protected under FDA’s gluten-free labeling rule (20 CFR. § 101.91), but this rule offers incomplete protection as it applies only to products *voluntarily* labeled gluten-free. For mainstream products without the gluten-free label, consumers have to play a kind of roulette in determining whether the products contain barley protein, which can be found in malt, malt extract, malt syrup, natural smoke flavor and more. In addition, the current guidelines don’t go far enough; research shows many adults and children on a strict gluten-free diet cannot completely avoid gluten and continue to suffer intestinal inflammation and extraintestinal symptoms.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7887593/) [2](https://journals.lww.com/jpgn/Fulltext/2017/02000/Value_of_IgA_tTG_in_Predicting_Mucosal_Recovery_in.23.aspx) [3](https://pubmed.ncbi.nlm.nih.gov/28644353/)

In the draft guidance, the FDA notes that “constant food vigilance and fear of accidental life-threatening reactions with every meal are daily, patient-centered challenges that can accompany management of IgE-mediated food allergy. These patient-centered challenges have been shown to negatively impact the quality of life of food allergic individuals and their caregivers.”

Beyond Celiac lauds the FDA’s recognition of this burden for those who have food allergies. Those with celiac disease also deserve recognition of the burden the gluten-free diet creates for them. They also face food vigilance and fear of accidental exposure with every meal, every day. Studies have shown a negative impact on the quality of life for children, adolescents and young adults. [4](https://pubmed.ncbi.nlm.nih.gov/31880669/) [5](https://pubmed.ncbi.nlm.nih.gov/29387990/) Although they may not suffer from anaphylaxis, they have severe and debilitating symptoms as a result of ingesting gluten, including seizures (epilepsy), dermatitis herpetiformis (historically called the “suicide rash” because of how painful it is) infertility, and certain cancers.

Most recently, research out of the University of Sheffield shows that gluten ingestion can cause white matter brain damage in patients with celiac disease. [6](https://www.gastrojournal.org/article/S0016-5085%2820%2930239-0/fulltext) Still more research shows that celiac disease has a burden comparable to end-stage renal disease. [7](https://pubmed.ncbi.nlm.nih.gov/24980880/) As celiac disease is a life-long condition, this is a lifelong burden—no one outgrows it, and there are no treatments that can desensitize a person with celiac disease to gluten, unlike some allergies. Because the only existing treatment for celiac disease is the gluten-free diet, those with celiac disease need accurate and complete labeling information to make safe decisions at the grocery store.

Finally, this draft guidance inexplicably goes directly against allergen recommendations made by the FAO/WHO Expert Committee regarding Risk Assessment of Food Allergens for Codex (cited in the FDA draft guidance at Ref.45) on May 10, 2021. The committee “determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac disease should be included on the list of foods and ingredients…” The committee confirmed that, in their expert opinion, gluten-containing cereals should always be declared in ingredient lists—in other words, not just wheat, but also barley and rye.

This isn’t news to the international celiac disease community. Many countries in Europe and around the world require the labeling of gluten to protect those who have celiac disease. Americans with celiac disease who travel to Europe often remark on how much easier it is to find safe, gluten-free grocery products, as well as restaurants providing safe, gluten-free meals. Conversely, those with celiac disease who travel to the United States find that it’s more difficult to find safe gluten-free food.

In short, it’s unclear why the FDA, a government organization whose purpose is to “protect the public health by [...] ensuring the safety of our nation's food supply,” would draft guidance that prohibits consumers, including those with celiac disease, from raising valid concerns about their policies and petition for worthwhile changes that would improve the safety of their food. This is in addition to resisting legislation supported by international experts, who recommend requiring gluten-containing grains be labeled on food products.

As a patient advocacy group, Beyond Celiac strongly opposes issuance of draft guidance FDA-2021-N-0553-0005. As a government organization, the FDA must serve the people, and, therefore, be willing to receive petitions on policies from citizens and advocacy groups. This includes petitions on foods that may cause an adverse, immune-mediated reaction. In addition, the FDA should not limit foods under FALCPA to those that cause IgE-mediated, life-threatening responses. Doing so would prevent millions of people with celiac disease, allergies, and food sensitivities from accessing safe food. Refusing to even consider providing protections for those with severe reactions to food is the antithesis of the FDA’s mission to protect consumers.

Beyond Celiac asks the FDA to consider our concerns, along with the concerns of community members and fellow advocacy groups, and work to provide safe products for the American people.

Thank you.

Sincerely,



Alice Bast
CEO, Beyond Celiac

Citations

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