

November 14, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dockets Management, FDA-2023-P-3942
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA Citizen Petition to Label Gluten as a Major Food Allergen
FDA Docket Number: FDA-2023-P-3942 ("Citizen Petition")

Dear Secretary Becerra and Commissioner Califf:

I am writing to strongly recommend that the FDA grant Celiac Journey's Citizen Petition to require the labeling of Gluten on all food packages in the United States,¹ just like Gluten is required to be declared on food labels in 87 other countries worldwide.²

Today, Wheat is required to be labeled in the U.S., but Gluten is not. Gluten is found in wheat, barley, and rye. This Citizen Petition is requesting a long-overdue reckoning by the FDA to better protect more than 3.3 million Americans with celiac disease, including me, by labeling Gluten (wheat, barley, and rye) as a Major Food Allergen on all packaged foods. Under its existing authority in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) in statute at 21 U.S.C. § 343(x), the Citizen Petition is requesting that the FDA issue a rule to: 1) require that all ingredients with Gluten be listed by name in the ingredient lists of all foods and; 2) add Gluten to the FDA's list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" to address both labeling and cross contact issues related to food manufacturing practices.

In addition to having the exiting authority, the FDA has the responsibility to require the labeling of Gluten as part of the FALCPA. The goal of the act is to improve consumer safety by labeling the most common allergens that affect individuals. It is also important to note that the FALCPA language from 2004 includes information about celiac disease in Section 202:

¹ <https://www.regulations.gov/document/FDA-2023-P-3942-0001>

² <https://farrp.unl.edu/IRChart>

“(A) celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs;
(B) the current recommended treatment is avoidance of glutens in foods that are associated with celiac disease; and
(C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population.”³

The prevalence of celiac disease is greater than 1% of the US population or 3 million individuals as noted by NIH.⁴ Clinical manifestations of celiac disease are immune mediated. The symptoms include gastrointestinal (ranging from severe malabsorption to subclinical damage of the gastrointestinal tract) as well as extraintestinal (e.g., skin) expressions of disease. Although rare, celiac disease is associated with increased risk of gastrointestinal tract cancers and lymphomas.”⁵

Food allergies are immune mediated reactions to foods. Allergies do not need to be IgE mediated, because these reactions can be either IgE mediated or non-IgE mediated. The classic IgE mediated reactions include hives (urticaria), oral allergy syndrome and anaphylaxis. Non-IgE mediated food allergies include food protein-induced enterocolitis, eosinophilic esophagitis and celiac disease.

While a non-IgE Mediated food allergy is not capable of triggering anaphylaxis and being *immediately* life-threatening. The severe adverse health effects that individuals with celiacs can develop through Gluten ingestion include anemia, cancer, heart disease, intestinal damage, malnutrition, etc.^{6 7} Celiac disease must be thought of as an immune-mediated food allergy and auto-immune disease.

As a member of the American Academy Allergy Asthma and Immunology and American College Allergy Asthma and Immunology and board certified allergist and researcher in the field of food allergy for the last 25 years, I have published over 300 peer-reviewed articles in this field. It is clear that food allergies include both IgE and non-IgE reactions. The non-IgE reactions are thought to be T cell mediated including celiac disease and Eosinophilic Esophagitis.

Consistent with the concept that food allergies are immune related reactions, the Ad hoc Joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) Expert Consultation on Risk Assessment of Food Allergens came to the conclusion in 2021 that, “*The Expert 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 included in section 4.2.1.4 of the GSLPF (General Standard for the Labelling of Packaged Foods).*”⁸

The 2021 FAO/WHO Expert Consultation found, “[b]ased on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their

³ <https://www.fda.gov/food/food-allergens/gluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa>

⁴ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

⁵ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

⁶ <https://www.fda.gov/media/157637/download>

⁷ <https://www.congress.gov/event/117th-congress/senate-event/LC65823/text?s=1&r=42> ; “Patient Perception of Treatment Burden is High in Celiac Disease Compared to Other Common Conditions,” PMC, National Library of Medicine, National Institutes of Health, July 1, 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159418/> ; Roy, A., Minaya, M., Monegro, M. et al. Partner Burden: A Common Entity in Celiac Disease. Dig Dis Sci 61, 34513459 (2016), <https://doi.org/10.1007/s10620-016-4175-5>; and “What is Celiac Disease?”, Celiac Disease Foundation, <https://celiac.org/about-celiac-disease/what-is-celiac-disease/>

⁸ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”⁹

With respect to labeling food products in the United States, the current voluntary Gluten Free labeling scheme that has been in place since August 5, 2014 does not sufficiently protect consumers who are on medically required and very restrictive Gluten Free diets. Recent research from Beyond Celiac has shown that 44% of people with celiac disease who follow a strict Gluten Free diet still get glutened once a month.¹⁰

Importantly, unlike food allergies with IgE mediated mechanisms, there is no rescue medicine (i.e., epinephrine or antihistamine) to treat accidental ingestion of Gluten and the start of the auto-immune cascade in food allergy with Non-IgE mediated mechanisms such as celiac disease. Additionally, those with a Non-IgE mediated food allergy to Gluten cannot outgrow their food allergy -- celiac is lifelong (until such time as a cure may be developed).

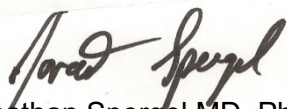
While U.S. consumers’ reactions to a top 9 Major Food Allergens and Gluten vary, their consumer habits are the same, they avoid purchasing foods that contain the allergen(s) that cause a potentially life-threatening immunological adverse reaction. They rely on food labels to know what is safe to eat.

However, the key difference from a consumer protection standpoint is that under FALCPA, the labeling scheme for the top 9 Major Food Allergens in the U.S. is mandatory, but the labeling of Gluten is voluntary. Just because something is Wheat free does not mean its Gluten Free. In other words, whereas sufferers of the current top 9 Major Food Allergens in the U.S. rely on what ingredients are expressly included in required labeling disclosures of packaged foods, the celiac community cannot rely on manufacturers to declare Gluten on food labels. This must change.

It is important that food allergies are both IgE and non-IgE mediated. The FDA under the FALCPA is required to recognize both. Your own experts in conjunction with the 2021 FAO/WHO Expert Consultation including the FDA’s Dr. Lauren Jackson, FDA’s Dr. Stefano Luccioli, Dr. Joseph Baumert, and Dr. Stephen Taylor did not adversely distinguish between IgE mediated and Non-IgE mediated food allergies in their systematic and thorough assessments which used all three criteria (prevalence, severity and potency) to determine the Risk Assessment of Food Allergens, the FDA must stop discriminating between IgE mediated and Non-IgE mediated food allergies with celiac when it comes to equitably evaluating the labeling of Gluten as a Major Food Allergen to protect 3.3 million American celiacs.

As someone who personally has celiac disease and as a physician whose career has been focused on treating pediatric allergy patients, I strongly believe that Gluten should be labeled as part of the FALCPA consistent with the labeling of Gluten in 87 other countries.

Sincerely,



Jonathan Spergel MD, PhD
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Chief, Allergy Section
Stuart E. Starr Chair of Pediatrics
Director of Center for Pediatric Eosinophilic Disease
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⁹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

¹⁰ <https://twitter.com/abast/status/1551780196243603457> and <https://www.beyondceliac.org/>