



Consumer Federation of America

May 8, 2024

Commissioner Robert M. Califf
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Support for Citizen Petition to Label Gluten as a Major Food Allergen
(Docket Number: [FDA-2023-P-3942](#))

Dear Commissioner Califf:

On behalf of Consumer Federation of America, I am writing in support of Celiac Journey's FDA Citizen Petition ("Citizen Petition") to require the labeling of gluten on all food packages in the United States. Nearly all of the United States' major trading partners require gluten labeling on food packaging, a policy endorsed by the International Codex Alimentarius Commission since 1999. Requiring food companies to label all gluten containing ingredients on packaging—not just wheat—and adding gluten to the FDA's list of common food allergens, would significantly improve the well-being of millions of U.S. consumers—nearly 1% of the population according to recent estimates—who suffer from celiac disease.¹

As the Citizen Petition points out, FDA rules currently require food manufacturers to label wheat, but not other gluten containing ingredients, such as barley, rye, and most oats, which tend to be contaminated with other gluten containing grains. As a result, millions of consumers with celiac disease must avoid a broad range of packaged foods, opting instead for expensive "certified gluten free" brands. Alternatively, these consumers must take on an unreasonable risk of suffering an allergic reaction to foods whose packaging gives no indication that they contain gluten. In addition to an array of immediate unpleasant symptoms, including diarrhea, stomach pain, weight loss, anemia, joint pain, and dermatitis herpetiformis—an itchy blistering skin rash, such exposure can cause permanent damage to the small intestine, resulting in a cascade of physical and mental health challenges.²

Hundreds of thousands of consumers recently benefitted from the addition of sesame to the list of eight "major food allergens" for which additional labeling rules apply. FDA should not wait for Congress to force it to act with respect to gluten, which is an allergen for many more consumers than sesame and several other of the "major allergens." As the Citizen Petition makes clear, FDA currently has ample authority to classify gluten as a major allergen, and to require food manufacturers to include a "contains gluten" statement on food labels. This is particularly essential

¹ <https://www.beyondceliac.org/celiac-disease/facts-and-figures/>

² <https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/symptoms-causes#dermatitis>

where otherwise opaque ingredients, such as “natural flavor” or “spice mix,” include sources of gluten.

Tens of millions of U.S. consumers have stopped eating gluten as a matter of dietary preference, and these consumers would undoubtedly benefit from better gluten labeling rules. However, the popularity of “gluten free” diets should not diminish the seriousness of gluten exposure to those with celiac disease. As advocates for consumers with allergies have argued, so-called “non-IgE-mediated food allergies” like celiac disease “are still real allergies.”³ Given the severity of celiac disease, the feasibility of better gluten labeling, as demonstrated in other countries, and the large number of celiac disease patients in the U.S. set to benefit from new FDA gluten labeling rules, the agency should not delay in taking the actions requested in the Citizen Petition.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

³ <https://www.foodallergy.org/fare-blog/why-we-need-stop-referring-ige-mediated-allergies-true-food-allergies>