



April 22, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.
Submitted via Regulations.gov

Re: [Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information \(Docket FDA-2023-P-3942\)](#)

To Whom It May Concern:

I am writing on behalf of The Asthma and Allergy Foundation of America (AAFA), the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world. We are dedicated to improving the quality of life for people with allergic diseases and asthma through education, support, advocacy and research. Kids with Food Allergies, a division of AAFA, offers tools, education, and community to families and children with food allergies across the country.

Because we know how important accurate ingredient labels are for people with food-related medical conditions, AAFA supports mandatory labeling in plain language of gluten-containing foods on food ingredient lists, as well as requiring cross-contact controls for gluten-containing grains.

Our experience with food labeling comes from years of policy advocacy for people with food allergies. In the United States, approximately seven percent of adults¹ and five percent of children² have food allergies – nearly 22 million people in total. The impact of food allergies has been growing; for example, across all age groups, the rate of emergency room visits for food-related anaphylaxis increased by 124% from 2005 through 2014.³

¹ Bottoms-McClain, L., Giri, A., & Ng, A. (2026). *Diagnosed Allergic Conditions Among Adults: United States, 2024*. Centers for Disease Control and Prevention, National Center for Health Statistics. <https://doi.org/10.15620/cdc/174634>

² Ng, A., Giri, A., & Bottoms-McClain, L. (2026). *Diagnosed Allergic Conditions Among Children Ages 0-17 Years: United States, 2024*. Centers for Disease Control and Prevention, National Center for Health Statistics. <https://doi.org/10.15620/cdc/174635>

³ Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005-2014." *J Allergy Clin Immunol Pract.* 2017 Jan - Feb;5(1):171-175.



Allergies are heterogeneous. Many people in our patient community have Immunoglobulin E (IgE) mediated allergies. IgE-mediated allergies are the “classic” food allergies that many people are familiar with; they can cause rapid symptoms throughout the body, including itching, hives, swelling, and vomiting, and a severe reaction called anaphylaxis (a medical emergency). Cell-mediated food allergies are a delayed hypersensitivity with symptoms primarily in the gut; this category includes Food Protein-Induced Enterocolitis Syndrome, or FPIES. Severe vomiting and diarrhea from a FPIES reaction can cause dehydration and hypovolemic shock – which requires immediate medical attention.

For our patient community, regardless of allergy type, accurate and complete labeling on food products is crucial. The 2004 Food Allergen Labeling and Consumer Protection Act, or FALCPA, established important standards for allergen labeling for eight major food allergens (peanut, tree nut, milk, egg, crustacean shellfish, finned fish, soy, and *wheat*), with sesame added in 2021. Under FALCPA, an ingredient containing any of the nine “major” allergens must be clearly named on the label of any FDA-regulated food, and manufacturing controls must be established to reduce the risk of cross-contact.

FALCPA has been the bedrock of food allergy management for millions of Americans. The label requirements allow people with one or more of the major nine food allergies to safely navigate packaged foods, and the manufacturing requirements make food safer by reducing the risk of accidental ingestion.

FALCPA’s Section 206 also directed the Secretary of Health and Human Services to issue a proposed rule by 2006 to define the term “gluten-free” on food labels. HHS issued the final rule on “gluten-free” labeling in 2013. Gluten is a protein found in wheat, barley, rye and their derivatives. The rule states that foods bearing the “gluten-free” claim cannot contain a gluten-containing grain above 20 parts per million (ppm) of gluten or it will be deemed misbranded.

While the FALCPA gluten rule helped define when a food could be labeled as “gluten free”, it notably did not address clearly labeling when foods *contain* gluten. This inconsistency between gluten labeling and allergen labeling can lead to confusion among food manufacturers, food handlers, and consumers – putting people with celiac disease (CD) at risk of consuming gluten-containing food. As such, gluten is nearly impossible to avoid



in packaged foods. Studies estimate that up to 3 out of 4 people with celiac disease are inadvertently exposed to gluten in food regularly.^{4,5,6}

Barley and wheat are also common FPIES triggers. But only one of these foods is required to follow the FALCPA labeling requirements to be clearly labeled on prepackaged foods, making barley allergy more difficult to manage.

Though CD is not an allergic condition, AAFA believes that people experiencing CD should benefit from analogous labeling and manufacturing requirements. As FDA notes, people with CD are able to rely on FALCPA's requirements regarding wheat. However, for other gluten-containing grains, there are no such requirements. Standardized labeling would reduce guesswork and research for people with CD. Similarly, good manufacturing processes to reduce CD cross contact will help people with CD minimize accidental exposures. Clearer labeling of gluten-containing foods would also benefit the smaller population of people managing barley or rye allergy (including FPIES).

Providing clear and accurate information about the food we consume helps people with food allergies, people with celiac disease, and many other Americans. AAFA supports this petition and looks forward to continued collaboration with the FDA to build on existing policies that boost the health of our patient community and others.

Sincerely,

Kenneth Mendez
President and CEO
Asthma and Allergy Foundation of America

⁴ Silvester JA, Comino I, Rigaux LN, et al. Exposure sources, amounts and time course of gluten ingestion and excretion in patients with coeliac disease on a gluten-free diet. *Aliment Pharmacol Ther.* 2020;52:1469–1479. <https://doi.org/10.1111/apt.16075>

⁵ Silvester JA, Graff LA, Rigaux L, Walker JR, Duerksen DR. Symptomatic suspected gluten exposure is common among patients with coeliac disease on a gluten-free diet. *Aliment Pharmacol Ther.* 2016 Sep;44(6):612–9. doi: 10.1111/apt.13725. Epub 2016 Jul 22. PMID: 27443825; PMCID: PMC5283559.

⁶ Beyond Celiac. *73% of celiac disease patients still exposed to gluten every year.* Beyond Celiac. Available at: <https://www.beyondceliac.org/blog/73-percent-still-exposed-gluten/>