April 16, 2026

Via Regulations.gov
Docket No. FDA-2023-P-3942

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Request for Information Regarding Labeling and Preventing Cross-Contact of Gluten in Packaged Food

To Whom It May Concern:

The Brewers Association (BA) is a 501(c)(6) not-for-profit national trade association that promotes and protects the interests of American craft breweries. We have more than 5,000 U.S. professional brewery members and over 1,200 supplier members from throughout the beer supply chain.

The BA appreciates the opportunity to comment on the FDA's RFI regarding labeling and preventing cross-contact of gluten in packaged food. We support truthful, accurate, and non-misleading labeling for consumers, including consumers with celiac disease and other gluten-related sensitivities. At the same time, we recommend that FDA not pursue new rulemaking or guidance that would expand current disclosure obligations.

FDA should not adopt any new gluten-related labeling or disclosure requirements unless those requirements are clearly grounded in the Federal Food, Drug, and Cosmetic (FD&C) Act. Clear statutory authority is especially important here because any attempt to expand disclosure obligations beyond the existing framework would invite legal uncertainty and potential legal challenges. Through the Food Allergen Labeling and Consumer Protection Act (FALCPA), Congress amended the FD&C Act to establish the current major-food-allergen framework, while FDA's separate gluten-related regulatory framework addresses use of the term "gluten-free."[1] This distinction is relevant because celiac disease is not the same as a food allergy. Celiac disease is a "chronic digestive and autoimmune disorder" triggered by gluten.[2] It

[1] Food and Drug Administration, "Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)," *U.S. Food and Drug Administration*. www.fda.gov.
[2] National Institute of Diabetes and Digestive and Kidney Diseases, "Definition & Facts for Celiac Disease," *National Institute of Diabetes and Digestive and Kidney Diseases*, U.S. Department of Health and Human Services. www.hhs.gov.

accordingly is not an IgE-mediated food allergy of the kind addressed through major-food-allergen labeling. Congress established distinct statutory and regulatory pathways, and FDA should not use this proceeding to blur them. FDA's own guidance continues to treat food allergens and gluten as distinct regulatory subjects.[3]

FDA should also avoid unsettling the agency's long-established 20 ppm gluten threshold. FDA adopted that standard in its gluten-free labeling rule and explained that foods labeled "gluten-free" must satisfy that benchmark along with the regulation's other conditions.[4] Food producers have made substantial investments in reliance on that standard, and any effort to revise it would create avoidable regulatory and operational disruption without a demonstrated basis. FDA therefore should retain the current threshold unless it has compelling scientific evidence for change.

For alcohol beverages, further FDA action is also inappropriate because the federal government already has a separate, product-specific framework administered by the Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB Ruling 2020-2 sets out a product-specific framework for gluten content statements on alcohol beverages, under which malt beverages made from gluten-containing grains may not bear an unqualified "gluten-free" claim and may use only limited, qualified statements under specified conditions.[5] Additionally, TTB is already considering allergen labeling through its ongoing rulemaking entitled Notice No. 238, *Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages*, and changes now could interfere with that process.[6] Any new FDA effort in these areas would risk duplicating, disturbing, or undermining TTB's framework.

The BA concludes that the existing regulatory framework established through the FD&C Act, FALCPA, and TTB already offers clarity and consistency for both consumers with celiac disease and regulated industry. Any additional federal action risks creating overlap, confusion, and unnecessary burden rather than a meaningful public-health benefit. For these reasons, the BA respectfully requests that FDA close this proceeding without proposing new rulemaking or guidance expanding gluten disclosure or cross-contact obligations.

Respectfully,

Marc Preo

Marc Preo
Special Projects Coordinator
Brewers Association

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[3] Food and Drug Administration, "Food Allergies," *U.S. Food and Drug Administration*. www.fda.gov.
[4] Food and Drug Administration, "Food Labeling; Gluten-Free Labeling of Foods," Federal Register 78, no. 150 (Aug. 5, 2013): 47154-47179.
[5] Alcohol and Tobacco Tax and Trade Bureau, "TTB Ruling 2020-2: Gluten Content Statements in the Labeling and Advertising of Wine, Distilled Spirits, and Malt Beverages," *Alcohol and Tobacco Tax and Trade Bureau*, 2020. www.ttb.gov.
[6] 90 Fed. Reg. 5763 (Jan. 17, 2025).