

Gluten-Free

Substantiation Requirements

This guide applies to products sold in the U.S. market. It is not intended to apply to products sold or marketed internationally.

Product Scope

These requirements are applicable to Food and Drug Administration (FDA) regulated food, consumables, and health & wellness products.

Background

Gluten is a mixture of proteins that occur naturally in wheat, rye, barley, and crossbreeds of these grains. Foods labeled as “gluten-free” and with similar terms such as “without gluten,” “free of gluten,” and “no gluten” must meet specific criteria set by the U.S. Food and Drug Administration (“FDA”). As one of the criteria for using the claim, the FDA set a limit of less than 20 ppm (parts per million) for the unavoidable presence of gluten in foods that carry the claim.

Claim Language

The requirements in this document are applicable to gluten-free claims and the following variants:

- No gluten
- Gluten-free
- Free of gluten
- Without gluten

Definitions

Gluten-Containing Grains: Per FDA regulations (21 CFR 101.91), a gluten-containing grain is one of the following grains or their crossbred hybrids:

1. Wheat, including any species belonging to the genus *Triticum*;
2. Rye, including any species belonging to the genus *Secale*; or
3. Barley, including any species belonging to the genus *Hordeum*.

Gluten-Free: Per FDA regulations (21 CFR 101.91), an item qualifies as “gluten-free” if it does not contain any of the following:

1. an ingredient that is a gluten-containing grain,
2. an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten; or
3. an ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food; or inherently does not contain gluten; **and**
4. Any unavoidable presence of gluten in the food is below 20 ppm gluten.

Omnichannel Requirements

The approved claim to be used in Walmart and Sam’s Club omnichannel initiatives is “**gluten-free**”.

Gluten-free claims **cannot** be inferred from an ingredient list or external sources.

Substantiation Requirements

Before representing a product as “gluten-free” in any omnichannel initiative, the Merchandising team must ensure that the following requirement is met:

- The gluten-free claim or any of the variants listed above is on the packaging

Additional Requirements

As part of the omnichannel initiative, the following or similar statement should be prominently displayed to consumers: “These products have been identified by the manufacturer as free of gluten. Always check the label to ensure the product aligns with your dietary preferences.” Modifications to this language should be escalated to Consumer Protection Compliance.

Exceptions

At this time, marketplace products are not allowed to participate in gluten-free omnichannel initiatives unless the product is also a 1P item.

Private Brand Requirements

The approved claim to be used on Walmart and Sam’s Club private brands packaging is “**gluten-free**”.

Substantiation Requirements

Before representing a private brand product as “gluten-free” on the packaging or in any omnichannel initiative, the supplier must ensure the following requirements are met:

- The supplier must complete and provide in the specification system a Supplier Acknowledgment of Expectations for the gluten-free claim, **and**
 - A third-party certification from a certifying body recognized by Walmart indicating the product meets the requirements outlined in 21 CFR 101.91. If a certification is provided, the document must be stored in Walmart’s or Sam’s Club’s product specification platform;
 - or**
 - An attestation letter outlining the policies and procedures in place to ensure that the final product meets the 21 CFR 101.91 requirements. If an attestation letter is provided, the document must be stored in Walmart’s or Sam’s Club’s product specification platform prior to third-party review. A third-party reviewing agency of Walmart’s or Sam’s Club’s choice will review the attestation to confirm it provides sufficient assurances that the final product contains less than 20 ppm of gluten.

Label Requirements

- The allergen statement or ingredient list cannot indicate that the product contains wheat.
- Consult the Proofing Standard or Brand Guide as it may contain additional brand requirements.

Exceptions

- Private brand products that contain grain or include an allergen advisory statement for wheat (e.g. “May contain wheat” or “Made in a facility that also handles wheat”), products packaged or prepared in-store, and products that are not packaged must be escalated to Consumer Protection Compliance and Regulatory Legal before making a “Gluten-Free” claim.

- USDA regulated products that contain the USDA-FSIS emblem of inspection and/or Establishment Number, are not within scope of this standard. Please escalate “Gluten-Free” claims to Consumer Protection Compliance and Regulatory Legal before making a “Gluten-Free” claim on USDA-FSIS products.



Ongoing Substantiation Requirements

- If a certification was provided the supplier must ensure the certification is maintained annually and stored in Walmart’s or Sam’s Club’s product specification platform.
- If an attestation letter was provided for substantiation, the supplier must submit a new attestation for third-party review every time the product is reformulated, or the label is updated and ensure the attestation letter is stored in Walmart’s or Sam’s Club’s product specification platform.

Recognized Certifications*¹

*Please refer to the Seals and Certification Standard for additional information.

- Gluten-Free Certification – BeyondCeliac.org
- Gluten-Free Certification Organization (GFCO)
- Gluten Free Food Program (GFFP)
- Gluten Intolerance Group (GIG)
- Informed Gluten-Free – BRCGS
- NSF Certified Gluten Free

¹ For private brand products’ certifications, Walmart Inc. must enter into a license agreement, along with the supplier.

Version History				
Version	Approved By	Revision Date	Description of Change	Author
1.0	Alissa Gardenswartz	4/24/2024	Original version was drafted.	Kathy Cuevas, Elizabeth Stoll
1.1	Alissa Gardenswartz	10/14/2024	Approved claim, additional label requirement, and omnichannel disclaimer.	Kathy Cuevas, Elizabeth Stoll