

Made Without

Substantiation Requirements [PRIVILEGED AND CONFIDENTIAL/ WORKING DRAFT]

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

Product Scope

These requirements are applicable to all products and packaging.

There may be specific claim standards that are maintained separate from this standard (ex. Gluten Free, Allergen Free, Sugar Free, etc.)

This standard applies to allergen free claims for animal food and feed products. All other “allergen free” claims should see the specific standard for that allergen.

Regulatory Requirements

If voluntary allergen-free claims are used, they must be truthful and not misleading in accordance with section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1))

21 CFR 201.64 - Sodium labeling of over-the-counter (OTC) drug products intended for oral ingestion may make a “sodium free” claim if the labeled maximum daily dose is 5 milligrams or less and the amount of sodium per dosage unit is 0 milligrams when rounded according to 21 CFR 201.64(b)

The section 260.9 of the FTC Green Guides state that a truthful “Free-of” claim may be deceptive if: (1) the product, package, or service contains or uses substances that pose the same or similar environmental risks as the substance that is not present; or (2) the substance has not been associated with the product category. In some circumstances a “free of” or “does not contain” claim is appropriate even if there is a trace amount of the specified substance if “(1) the level of the specified substance is no more than that which would be found as an acknowledged trace contaminant or background level; (2) the substance’s presence does not cause material harm that consumers typically associate with that substance; and (3) the substance has not been added intentionally to the product.” The FTC does not define what qualifies as a trace amount or background level but has stated that such analysis is case-by-case.

Claim Language

The requirements in this standard are applicable to “made without” claims and the following variants:

- _____(ingredient) Free
- Does not contain_____(Ingredient)
- No_____ (ingredient)
- Formulated without_____(ingredient)

***Refer to the claim specific standard if one has been drafted (ex. Nut Free, Fat Free Sodium Free, Sugar Free, etc.).**

Omnichannel Requirements

The approved claim to be used in Walmart and Sam’s Club omnichannel initiatives is “made without [**specific** ingredient/component]” or “free from [specific ingredient/component].”

“Made without” claims **cannot** be derived from an ingredient list, or external sources.

Substantiation Requirements

Before representing a product as “made without” in any omnichannel initiative, the Merchandising team must ensure the following requirement is met:

- The “made without” claim for the relevant ingredient, preservative, flavor, color, or component or one 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 “made without” a specific ingredient or component. Always check the label to ensure the product aligns with your preferences.” Modifications to this language should be escalated to Consumer Protection Compliance.

Private Brand Requirements

The approved claim to be used in Walmart and Sam’s Club private brand packaging is “made without” or “free from” followed by the relevant ingredients, preservatives, flavors, colors, or components.

Substantiation Requirements

Before representing a private brand product as “made without” 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 “made without” claim, **AND**
 - Food and Dietary Supplement Products: A third-party certification or formulation review by a third-party of Walmart/Sam’s Club choosing to confirm:
 - The product does not contain more than a trace level of the substance (and confirm what trace amount means in the context of the product category),
 - Where the trace amount of the substance came from, if applicable, **AND**
 - That the product does not contain substances similar to the free-of substance, **AND**
 - For OTC Products making a “Sodium Free” claim, confirmation the product meets the requirements of 21 CFR 201.64
 - Non-Food Products: A third-party certification or test report by a third-party lab which Walmart Product Safety Compliance has recognized supporting the following:
 - The product does not contain the substance, **AND**
 - That the product does not contain substances similar to the free-of substance.

Label Requirements

- The ingredients or components the product is “made without” must be disclosed in proximity to the claim.
- Refer to the Proofing Standard or Brand Guide for brand requirements.

Exceptions

- The requirements in this document are not applicable to “made without” or “free from” claims with dedicated standards. Please refer to the specific standards for the requirements applicable to those claims (ex. Gluten Free, Nut Free, Fat Free, Sodium Free, Sugar Free, etc.)
- Even if true, a “made without” claim is not permissible if the substance that the product is “made without” has not been associated with the product category.

Ongoing Substantiation Requirements

- If the formulation was reviewed, the supplier must send the formulation to a third-party reviewing agency of Walmart/Sam’s Club’s choice for review every time the product gets reformulated, or label updated.
- If a certification or test report were provided, the supplier must ensure the certification is maintained annually and 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.

- EWG Verified

Continuing Obligation to Defend and Indemnify

As a private brand supplier to Walmart Inc., the supplier is solely responsible for the accuracy of all product labeling and claims. Compliance with the requirements outlined in the “Product and Packaging Claims - Substantiation Requirements for Private Brands”, or any label review conducted by or at the request of Walmart Inc., in no way impacts contractual defense and indemnity obligations to Walmart Inc. as set forth in the Supplier Agreement for all claims related to merchandise, including claims related to the labeling.

Version History				
Version	Approved By	Revision Date	Description of Change	Author
1.0			Original version was drafted.	Nathan Traw

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