

Questions and Answers on Health Claims in Food Labeling

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Health claims in food labeling are claims that have been reviewed by FDA and are allowed on food products to show that a food or food component may reduce the risk of a disease or a health-related condition. Such claims are supported by scientific evidence and may be used on conventional foods and on dietary supplements to characterize a relationship between a substance (a specific food component or a specific food) and a disease or health-related condition (e.g., high blood pressure). The Nutrition Labeling and Education Act of 1990 (NLEA) directed FDA to issue regulations providing for the use of health claims. All health claims must undergo review by the FDA through a petition process.

Health claims:

- must contain the elements of a substance and a disease or health-related condition;
- are limited to claims about disease risk reduction;
- cannot be claims about the diagnosis, cure, mitigation, or treatment of disease; and
- are required to be reviewed and evaluated by FDA prior to use.

There are two types of health claims: “authorized” and “qualified” health claims.

Authorized Health Claims

1. What is an "authorized" health claim?

To be approved by the FDA as an authorized health claim, there must be significant scientific agreement (SSA) among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship.

An example of an authorized health claim is, "Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life."

2. What is "significant scientific agreement?"

When the FDA evaluates a health claim, the agency considers the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles). If there is significant scientific agreement (SSA) among qualified experts that the claim is supported by the evidence, the agency will authorize by regulation a health claim for the substance/disease relationship.

As stated in the Final Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims (</food/guidance-documents-regulatory-information-topic/guidance-industry-evidence-based-review-system-scientific-evaluation-health-claims>), the SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship.

3. Doesn't the significant scientific agreement standard make it difficult for any claim to be made?

The significant scientific agreement standard reflects the need for a reasonable degree of certainty that the science supporting a health claim is unlikely to change. View the current list of authorized health claims (</food/labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard>).

4. Has the FDA ever revoked an authorized health claim?

The FDA has authorized 12 health claims (/food/labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard#Approved_Health_Claims) since 1990. On October 31, 2017, the agency issued a proposed rule (<https://www.federalregister.gov/documents/2017/10/31/2017-23629/food-labeling-health-claims-soy-protein-and-coronary-heart-disease>) to revoke the regulation that authorizes the use of a health claim about the relationship between soy protein and the reduced risk of coronary heart disease. This was based on a review of the totality of the publicly available scientific evidence that led the FDA to tentatively determine that the current evidence for the health claim about the relationship between soy protein and the reduced risk of coronary heart disease no longer meets the Significant Scientific Agreement standard necessary for an authorized health claim.

For more information about the proposed rule, visit: FDA Proposes to Revoke Authorized Health Claim Regarding Soy Protein and Reduced Risk of Coronary Heart Disease (</news-events/press-announcements/statement-susan-mayne-phd-proposal-revoke-health-claim-soy-protein-reduces-risk-heart-disease>).

5. Where can I find a list of authorized health claims?

Visit [Authorized Health Claims That Meet Significant Scientific Agreement \(/food/labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard\)](#) for a list of FDA's authorized health claims.

Qualified Health Claims

1. What is a “qualified” health claim?

Qualified health claims are supported by some scientific evidence, but do not meet the significant scientific agreement standard. To ensure that they are not false or misleading to consumers, qualified health claims must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. Qualified health claims are currently evaluated under the FDA's interim guidance ([/food/guidance-documents-regulatory-information-topic/guidance-industry-interim-procedures-qualified-health-claims-labeling-conventional-human-food-and](#)) for such claims.

An example of a qualified health claim is, “Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2.”

2. How did qualified health claims develop?

In response to litigation that raised First Amendment challenges to the significant scientific agreement standard, the FDA in 2000 announced its intention to exercise its enforcement discretion with regard to certain categories of dietary supplement health claims that may not meet this standard. In 2002, the FDA extended this approach to health claims on conventional foods. The assumption underlying this approach is that disclaimers will remedy any potential harm caused by potentially misleading claims.

In 2003, through the Task Force Report for the Consumer Health Information for Better Nutrition Initiative ([/food/labeling-nutrition/consumer-health-information-better-nutrition-initiative-task-force-final-report](#)), the FDA made available two interim guidance documents to update the agency's approach to regulating qualified health claims. The final versions of these guidances are available here: "Guidance for Industry: Evidence-based Review System for the Scientific Evaluation of Health Claims ([/food/guidance-documents-regulatory-information-topic/guidance-industry-evidence-based-review-system-scientific-evaluation-health-claims](#))" and "Guidance for Industry: FDA's Implementation of “Qualified Health Claims”: Questions and Answers; Final Guidance

(/food/guidance-documents-regulatory-information-topic/guidance-industry-fdas-implementation-qualified-health-claims-questions-and-answers-final-guidance)".

3. Does the FDA review qualified health claims?

Yes. All health claims, whether authorized or qualified, require pre-market review by the FDA. Under federal law, the FDA approves by regulation authorized health claims for use in food labeling only if the substance/disease relationship described by the health claim meets the "significant scientific agreement" standard. For qualified health claims, the FDA issues letters of enforcement discretion when there is credible evidence to support the claim.

4. What process does the FDA use to review qualified health claims?

The FDA follows the process outlined in two guidance documents, entitled "Guidance for Industry: Evidence-based Review System for the Scientific Evaluation of Health Claims (/food/guidance-documents-regulatory-information-topic/guidance-industry-evidence-based-review-system-scientific-evaluation-health-claims)" and "Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance (/food/guidance-documents-regulatory-information-topic/guidance-industry-fdas-implementation-qualified-health-claims-questions-and-answers-final-guidance)." These guidance documents describe a process and procedure for the FDA to systematically evaluate and rank the scientific evidence relevant to a substance/disease relationship that is the subject of a qualified health claim. Different levels of scientific evidence result in different qualifying language for a claim. The qualifying language provided by the agency's guidance serves as an example for petitioned qualified health claims and may vary depending on the specific circumstances of each substance/disease relationship.

5. Where can I find a list of the FDA's qualified health claims?

Visit Qualified Health Claims: Letters of Enforcement Discretion (/food/labeling-nutrition/qualified-health-claims-letters-enforcement-discretion) for a list of current qualified health claims. See letters of denial and withdrawal of qualified health claim petitions (/food/labeling-nutrition/qualified-health-claims).