

Whey Protein & Muscle Benefits Messaging

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This document summarizes key information regarding developing messages for whey protein and muscle.

Reference Guide

Regulatory Affairs
Dairy Research Institute

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Introduction: Whey Protein and Muscle Benefits Messaging

This **Reference Guide** provides a general overview of nutrition labeling terms and requirements associated with use of messages about whey protein and the function of muscles.

These messages may be considered for use in various types of communications. Compliance with regulatory requirements and industry standards set forth by the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC) and other governing agencies is critical.

The term “labeling” is defined broadly in the Food, Drug and Cosmetic Act (section 201(m)) as ‘*all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.*’ FDA has indicated that labeling is not limited to actual labels on a food product, but also includes “brochures, booklets...motion picture films, film strips, sound recordings ... and similar pieces of printed, audio, or visual matter ... which are disseminated by or on behalf of its manufacturer, packer, or distributor...” Thus, products that are promoted through written, printed, or graphic matter that supplement or explain the product for use in the distribution and sale of the product, such as flyers and brochures in proximity to a product on a shelf in a grocery store, are likely to be considered “labeling.” FDA has also indicated that information provided on a website that offers a product for sale, meaning that the product can be ordered through the site for delivery or when the product links to such a site, will be viewed as labeling. [Source: Food Regulation. Law, Science, Policy, and Practice. Neal D. Fortin, J.D. Published by John Wiley & Sons, Inc. Hoboken, New Jersey. 2009]

The FTC is responsible for protecting consumers from unfair or deceptive acts or practices and oversees food advertising, which includes materials available on the Internet. FTCs oversight broadly covers advertising materials, promotional activities, and marketing and sales practices in general and includes traditional print, television, telephone and radio advertising and well as materials provided on the internet for the purposes of promoting the sale of a product. The FTC periodically joins with other law enforcement agencies to monitor the Internet for potentially false or deceptive online advertising claims. When advertising materials do not comply with the law, enforcement actions or civil lawsuits may be taken.

The FTC requires that advertising materials be truthful and not misleading and that advertisers have supportive evidence (substantiation) to back up their claims. A claim may be considered misleading if relevant information is left out or if the claim implies something that's not true. A claim can be considered unsubstantiated without adequate documented

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support. FTC has published a number of rules and guidance documents to help businesses comply with the law (e.g. Enforcement Policy Statement on Food Advertising; FTC Policy Statement Regarding Advertising Substantiation; Advertising and Marketing on the Internet Rules of the Road; Dietary Supplements An Advertising Guide for Industry; Statement of Policy Regarding Comparative Advertising); for more information see <http://www.ftc.gov/bcp/guides/guides.shtm>.

This **Reference Guide** provides a general overview of nutrition labeling terms and requirements associated with use of messages for claims about whey protein on food labels or in labeling. See the companion **Scientific Backgrounder** for a summary of scientific research that support messages about whey protein and muscle benefits. This **Reference Guide** is only intended as a general summary of information and is not intended to take the place of either the written law or regulations. Since regulations may change over time, it is important to consult the most current regulations prior to making any claims. The Dairy Research Institute expresses no opinion about the suitability of the information for use and suggests that any recipient obtain appropriate expert advice with regard to any statements or information herein contained (see *footer*).

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Whey Protein & Muscle Protein Benefits

Whey Protein – General Claims

Whey Protein

- can help build and maintain muscle

Whey Protein as part of an Exercise Program

Consuming whey protein in combination with resistance exercise can boost the rate at which the body makes lean muscle, which may improve body composition.

When included as part of your weight training program, whey protein, a high quality protein,

- helps promote muscle repair and recovery after exercise
- helps repair muscles (more completely) after a workout
- helps nourish your muscles after a workout
- helps rejuvenate your muscles after a tough workout
- helps build new muscle and reduce muscle breakdown
- can help you bulk up
- help make the most of your workouts
- can help you meet your weight training goals
- helps build lean muscle

Whey Protein and Muscle Benefits Structure/Function Claims

There are no FDA preapproved claims for dietary protein and muscle benefits. Structure/function claims, which describe the role of a nutrient on the normal structure or function of the body, may be made. Structure/function claims imply that the food product contains at least a good source of the nutrient for which the label claim is made. Good sources are defined as containing 10-19% of the Daily Value per reference amount customarily consumed (RACC), which corresponds to 5 - 9 grams of protein per RACC. Excellent sources are defined as providing 20% or more of the Daily Value per RACC, which corresponds to 10 grams or more of protein per RACC.

As guiding principles, structure/function claims should be truthful and not misleading, based on the nutritive value of the ingredient or dietary component and substantiated based on competent and reliable evidence. The Dairy Research Institute has prepared a summary of authoritative statements and scientific evidence in support of messages and claims such

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as those shown above in the companion *Scientific Backgrounder*. The wording of label claims is at the discretion of the food manufacturer, thus, other label claims unique to a brand may be developed, in accordance with on the existing scientific support science.

All claims should comply with federal regulations and guidelines.²

Examples of possible structure/function claims for protein / whey protein for muscle benefits are shown above.

Qualifying amount of protein

FDA specifies that structure/function claims should be based on a meaningful amount of the nutrient or dietary substance in the product⁵. For protein, 10% of the Daily Value or more may be considered a meaningful amount. This amount is consistent with the qualifying criteria for a nutrient content claim as established by FDA. The Daily Reference Value of protein for adults and children over 4, which forms the basis for calculating the Daily Value, is 50 grams⁶.

Therefore, foods that contain at least 5 g of protein, including whey protein, per reference amount (RACC) of the food can qualify for structure/function and nutrient content claims for protein. Products containing whey protein exclusively as the protein source also can qualify, dependent on the total amount of protein per RACC.

For labeling purposes, declaration of the percent daily value (%DV) is not required unless the protein content of the food is of low quality based on the *protein digestibility-corrected amino acid score* (PDCAS). Manufacturers may voluntarily include the %DV for protein, however, if reported, the value must be based on the PDCAS score. (see 21 CFR 101.9). The PDCAS value is used together with the g of protein to derive the %DV for protein in a food. Determination of the PDCAS value requires rather expensive and sophisticated analyses, so many foods, including those that do not have complete protein, do not report %DV.

Protein Messages and Nutrient Content Claims for Protein

Nutrient content claims, established by federal regulations, can accentuate the product's strongest nutritional selling point. Nutrient content claims use descriptors to characterize how much of a specific nutrient or dietary substance is in that food. Though not required by federal regulation, it is advisable to include nutrient content claims when making structure/function claims, including those mentioned here within. The following nutrient content claims may be made on food labels with protein and may accompany structure function claims:

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- An *excellent source* claim can currently be made for protein on any food or beverage containing 20% or more (at least 10 grams) of the Daily Value for protein per RACC³. Examples of these claims include:
 - High in protein
 - Rich in protein
 - Excellent source of protein
- A *good source* claim can currently be made for protein on any food or beverage containing 10-19% (5-9 grams) of the Daily Value for protein per RACC.³ Examples of these claims include:
 - Good source
 - Contains
 - Provides
- Claims highlighting the addition of protein to foods through fortification can currently be made on any food or beverage containing an additional 10% (at least 5 grams) or more of the Daily Value for protein per RACC.³ Examples include:
 - More
 - Fortified
 - Enriched
 - Added
 - Extra
 - Plus

Disclosure Statement

A “*disclosure statement*” is required when a nutrient content claim is made and the food contains one or more of the following nutrients at levels that exceed 13 g for total fat, 4 g for saturated fat, 60 mg for cholesterol, and 480 mg for sodium per labeled serving and per reference amount customarily consumed (and per 50 g for foods with reference amounts of 30 g or less or 2 tbs)⁴. The disclosure statement should state, “See nutrition information for [nutrient requiring disclosure] content.”

Nutrient disclosure levels are not required on products making only structure/function claims. It is advisable, however, for structure/function claims to follow the disclosure criteria for nutrient content claims.

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Appendix

The following sections are verbatim from the Quick Reference Guide: Nutrition Claims for Dairy Foods (2009) and are provided here for convenience. The following information is intended to be a general summary of information, and is not intended. The following information is intended to be a general summary of information, and is not intended to take the place of either the written law or regulations. For an authoritative source, the FDA Regulations are published in the CFR (Code of Federal Regulations) and are available on line and in book format from the Superintendent of Documents, US Government Printing Office. References to specific sections of the federal regulations are provided for informational purposes.

Structure/Function Claims

Structure/function claims describe the effect of a nutrient or substance on the normal structure or function of the body (e.g., calcium builds strong bones) and may be used on food products without prior FDA approval. However, like all information on a food label, they must be truthful and not misleading. Current FDA policy permits structure/function claims on conventional foods if their claimed benefit derives from the food's nutritive value.

Guidance on FDA's position may be found in a published final rule on structure/function claims for dietary supplements [65 FR 999 – 1050. January 6, 2000]. Although the final rule focuses on dietary supplements, FDA stated in the preamble that the basic requirements would also apply to structure/function claims made for conventional foods. FDA also provides criteria to assist in determining when a statement is a disease claim, that is, a claim to diagnose, cure, mitigate, treat, or prevent disease (<http://www.cfsan.fda.gov/~dms/sclmguid.html>). The manufacturer should have substantiation, defined as competent and reliable scientific evidence, for any structure/function claims on label or in promotional/advertising materials (<http://www.cfsan.fda.gov/~dms/sclmguid.html>). FDA provides guidance to assist manufacturers on making structure/function claims on food labels (<http://www.cfsan.fda.gov/~dms/labstruc.html>).

While regulations do not prohibit the use of structure/function claims on foods that exceed the nutrient disclosure levels set for fat, saturated fat, cholesterol and sodium, it is advisable to adhere to these values and disclose if they exceed 13 grams of fat, 4 grams of saturated fat, 60 milligrams of cholesterol or 480 milligrams of sodium per reference amount and per 50 grams if the reference amount is 30 grams or less.

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Nutrient Content Claims

A nutrient content claim on a food product defines how much of a specific nutrient or dietary substance is in that food. It does not link that nutrient with a specific disease or health-related condition. Nutrient content claims can only be made if a food product meets the criteria set by the FDA.

FDA permits the use of factual statements that disclose the amount of a nutrient in a product provided that such a statement does not implicitly characterize the level of a nutrient and is not false or misleading (e.g., 100 calories or 5 grams of fat).

When making a nutrient content claim for a qualifying product, keep the following general requirements in mind:

- Dairy products making a nutrient content claim must carry nutrition labeling.
- The “**reference amount**” rather than the “**label serving size**” must be used when determining whether a product meets the criteria for a nutrient content claim.
- A nutrition claim may not be larger than twice the type size of the statement of identity (*product name*).
- If the product has been altered, reformulated or processed in order to qualify for a nutrition claim, the modified product must be nutritionally equivalent to the regular product. This may require fortifying the product. Otherwise, it must be labeled as an “imitation” food.
- FDA requires that the performance characteristics of a nutritionally modified food must be similar to the food for which it substitutes. Performance characteristics are organoleptic, physical and functional attributes. Information on any material difference in performance characteristics must be provided on the label. [21 CFR 101.13(d)(i)]
- A “**disclosure statement**,” if applicable, must appear close to the nutrient content claim. (*See page [xx]*)

A “disclosure statement” is required when a nutrient content claim is made and the food contains one or more of the following nutrients in excess of the level listed below. These nutrient levels are also the amounts that must not be exceeded per reference amount and per labeled serving for FDA-approved health claims (termed “**disqualifying nutrients**”). For more information, see the section on “Health Claims.”

| Disclosure/ Disqualifying Nutrients | Disclosure/Disqualifying Level per Reference Serving Size |
|--|--|
| Total Fat | 13 grams |
| Saturated Fat | 4 grams |
| Cholesterol | 60 milligrams |
| Sodium | 480 milligrams |

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The disclosure statement must appear prominently and in immediate proximity to the claim with no intervening material. If the claim appears on more than one panel, the disclosure statement must accompany it except when the claim appears on the panel that bears the nutrition information, in which case the disclosure statement may be excluded.

The disclosure statement should read as follows: “See nutrition information for [nutrient requiring disclosure] content.” These levels must not be exceeded per reference amount or per labeled serving without making the required disclosure statement. Foods with a reference amount of 30 g or less or 2 tbsp or less must not exceed the designated levels per 50 g of product or the disclosure statement will be required. Detailed information on the requirements for the disclosure statement can be found in the nutrient content section at <http://www.cfsan.fda.gov/~dms/2lq-toc.html> or [21 CFR 101.13(h)(1)-(3)]

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