

# **Claims for Food Labels**

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## **Health Claims**

In 1993, FDA published the final rule implementing the Nutrition Labeling and Education Act (NLEA) of 1990 (1). Among the regulations was a revision of the list of required nutrients and food components and the conditions for declaring them in nutrition labeling. It also requires that food labels that bear health claims and/or nutrient content claims comply with specific requirements. NLEA provided the FDA with an authorization of health claims under the significant scientific agreement (SSA) standard. Health claims are about a causal relationship between a substance (food or food component) and reduction in the risk of a disease or health-related condition for the general U.S. population or subpopulation. They are not about treatment, prevention, curing, or mitigating a disease because these are drug claims. There are two mechanisms for obtaining a health claim, petition the agency or submit a notification based on an authoritative statement from certain federal scientific bodies, as well as from the National Academy of Sciences. The later was enacted through the Food and Drug Administration Modernization Act (FDAMA) of 1997 (2). This was intended to expedite the process by which the scientific basis for such claims is established.

General requirements for health claims are described in regulation 21 Code of Federal Regulation (CFR) 101.14. The general health claim regulation has set specific requirements for threshold levels of certain nutrients (i.e., total fat, saturated fat, cholesterol, or sodium) above which the food is disqualified from using the claim. Except for a dietary supplement, a food may not use a health claim unless the food contains at least 10 percent of the Daily Value (DV) for one or more of six specific nutrients (vitamin A, vitamin C, iron, calcium, protein or dietary fiber) per reference amount customarily consumed (RACC).

The significant scientific agreement standard is when it has been determined, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, and that the claim is supported by such evidence (3). There is a continuum of scientific discovery that extends from emerging evidence to one in which there is a strong consensus for the relationship. Examples of relevant authorized health claims include fiber-containing grain products, fruits, and vegetables and cancer (see 21 CFR 101.76); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (CHD) (see 21 CFR 101.77); and dietary saturated fat and cholesterol and risk of CHD (see 21 CFR 101.75).

## **Qualified Health Claims**

Several dietary supplement manufacturers challenged in court the FDA decision to apply the significant scientific agreement standard to dietary supplements. The Court directed FDA to permit, in certain circumstances, the use of dietary supplement health claims not meeting SSA. The Court concluded that First Amendment protection of commercial speech does not permit the FDA to prohibit dietary supplement health claims that the agency determined to be potentially misleading unless the agency could also determine that adding a disclaimer to the claim would not eliminate the potential deception. In December, 2002, the former FDA commissioner, Dr. Mark McClellan, announced a major new initiative, “The Consumer Health Information for Better Nutrition Initiative” (4). This initiative’s central focus was to improve the public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health. This initiative provided for the use of qualified health claims for both conventional foods and dietary supplements. An FDA Task Force was formed, and within six months it developed a regulatory framework for qualified health claims in the labeling of conventional foods and dietary supplements, provided guidance for an interim evidence-based ranking system for scientific data (5), provided guidance for interim procedures for qualified health claims in the labeling of conventional food and dietary supplements (6) and developed a consumer studies research agenda. The process for reviewing the scientific evidence for an SSA level health claim and a qualified health claim is the same.

## **Nutrient Content Claims**

Nutrient content claims are claims on the label or labeling of foods that expressly or implicitly characterize the level of a nutrient in the food, which was established by NLEA. These claims are defined by regulation (see 21 CFR 101.13 – general principles). They apply to nutrients that have an established Daily Value. The level of a nutrient in a food may be characterized using descriptive terms such as “low”, “reduced”, “free”, “good” or “excellent source” of, as well as others, for specific nutrients. For example, a “good source” of fiber means that the level is 10% to 19% of the DV per serving. For nutrients without an established DV, the use of quantitative statements may be used, such as “10 grams of whole grain”. These type of statements may be used provided that the statement does not use language that characterizes the amount. A disclosure statement is required if the food exceeds prescribed levels of fat, saturated fat, cholesterol or sodium.

## **Other Claims**

Food labels may use claims about the effects of food on structures or functions of the body. These claims cannot be about a disease or implied disease. The Dietary Supplement Health and Education Act (DSHEA) (7) clarified the difference between the regulation of health claims and structure/function claims for dietary supplements. An example of a structure/function claim would be “calcium builds strong bones”. There is no mention of a disease, but the substance, calcium, is identified in the claim language.

Dietary guidance or health messages refer to statements about general dietary patterns, are not about a specific substance, but a broad category of food, e.g., fruits and vegetables, and are about promoting good health. For example, “choose fiber-rich fruits, vegetables, and whole grains often” would be considered a dietary guidance statement. These statements must be truthful and not misleading, as with all label information. They are not regulated as health claims as they are not about a specific food or component of food.

## References

1. Nutrition Labeling and Education Act of 1990, November 8, 1990. Public Law 101–535, November 8, 1990.
2. Food and Drug Administration Modernization Act of 1997. Public Law 105-115. November 21, 1997. Available at <http://www.fda.gov/oc/fdama/>.
3. US Food and Drug Administration. Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements. 1999: 1 -21. Available at: <http://www.cfsan.fda.gov/~dms/ssaguidehtml>.
4. US Food and Drug Administration. Consumer Health Information for Better Nutrition Initiative. Task Force Final Report. July 2003. Available at <http://www.cfsan.fda.gov/~dms/nuttfoc.html>.
5. US Food and Drug Administration. Guidance: Interim Evidence-Based Ranking System for Scientific Data. Consumer Health Information for Better Nutrition Initiative Task Force Final Report. July 2003:B-1-B-13. Available at: <http://www.cfsan.fda.gov/~dms/nuttf-b.html>.
6. US Food and Drug Administration. Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. Consumer Health Information for Better Nutrition Initiative Task Force Final Report. July 2003:E-1-E-5. Available at: <http://www.cfsan.fda.gov/~dms/nuttf-e.html>.
7. Dietary Supplement Health and Education Act of 1994. Public Law 103-417. October 25, 1994. Available at <http://www.fda.gov/opacom/laws/dshea.html>.