
BITS, BRIEFS, AND APPLICATIONS

BRIAN WANSINK AND MATTHEW M. CHENEY

Leveraging FDA Health Claims

Although past research has investigated different aspects of various health claims, relatively little effort has been directed toward synthesizing the reasons why some Food and Drug Administration (FDA) health claims are more successful than others. After outlining two necessary conditions for a health claim's success, currently approved FDA health claims are examined to explain both the diet–health relationship and its effect on the widespread awareness and adoption of the claim. Understanding what makes health claims successful provides useful nutrition education and product-labeling lessons for policy makers in all countries.

A health claim characterizes the relationship between a food nutrient and the risk of a disease or health-related condition (*Federal Register* 1993). These claims can alert consumers to a product's health potential by stating that certain foods—as part of an overall diet—may reduce the risk of certain diseases (Hurt and Crocco 1986). Such efforts, however, are not always successful (Caswell and Mojduzka 1996; Caswell and Padberg 1992). This research examines how the varying degrees of success of FDA health claims can provide insights that can help food regulatory agencies in all nations be more effective and influential in their nutrition education and product-labeling efforts.

Past research on health claims has typically focused on a consumer's perceptions of a health claim's believability, simplicity, or clarity (Levy 1995; McMahon 1996; Silverglade 1991). While past studies suggested that when consumers processed health claim information, they seldom examined how any resulting lessons could be used to encourage the increased consumption of the healthy foods (Wansink 2005).

Brian Wansink is a professor of nutritional science, business administration, advertising, and agricultural and consumer economics at the University of Illinois at Urbana-Champaign. He is also a John S. Dyson Professor of marketing, applied economics, and nutritional science at Cornell University, Ithaca, NY (wansink@cornell.edu). Matthew M. Cheney is a graduate student at the Graduate School of Library and Information Science, University of Illinois at Urbana-Champaign.

The authors would like to thank Greg Locke, Steven Sonka, Se-Bum Park, Clare Hasler, Michelle Morganosky, and the Illinois Council for Agricultural Research for their support of this project.

This paper is organized as follows. First, we review how consumers learn about health claims and how their awareness of the diet–health relationship influences the acceptance of these claims. Second, the successes and failures of FDA health claims are analyzed to show how they can best facilitate the consumption of healthy foods. Last, implications for nutritional education, labeling, and marketing are illustrated in the context of soy health claims.

FDA HEALTH CLAIMS AND THE DIET–HEALTH RELATIONSHIP

Consumers receive information about health claims from a variety of sources. Product nutritional labels are a primary source of this information (Bender and Derby 1992; Feick, Herrmann, and Warland 1986), supplemented by point-of-purchase displays, special educational campaigns (e.g., Five-A-Day), friends, family, and fitness professionals. Since the information provided by nutritional labels is sometimes viewed by consumers as misleading and unclear (Porter et al. 1998), it has increasingly become a function of other sources (such as academia, government entities, public health communities, and medical practitioners) to provide credibility to health claims from their own particular perspective.

Why Consumers Do Not Internalize Health Claims

Changes made by the Nutrition Labeling and Education Act were intended to make nutritional information more useful and informative by changing the way the information was presented on food labels (Caswell 1992). In spite of these efforts, many consumers still believe that FDA-approved health claims are too vague, wordy, academic, and long (McMahon 1996). It has been suggested that consumers neither use nor comprehend nutritional information in their food purchase decisions because they are skeptical of health claims (Szykman, Bloom, and Levy 1997) or perceive them as incomplete or misleading (Silverglade 1991).

Despite this general confusion with nutritional labeling, there are instances when consumers are able to accurately evaluate health claims and the information from the nutritional fact panel (Ford, Smith, and Swasy 1990; Ippolito and Mathios 1991). By building on these past successes, health claims can be developed, formatted, and disseminated in a way that facilitates a consumer's interpretation, belief, and use of information on product labels.

How Consumers Come to See a Relationship between Diet and Health

Knowledge about nutrition only influences eating habits when a person is motivated to act on it (Blaylock et al. 1999). At a basic level, there are two fundamental types of knowledge consumers can have about nutritional food—its attributes and its benefits (Wansink, Westgren, and Cheney 2005). First, consumers can have knowledge about a particular food's nutritional properties or attributes, such as its vitamin A content or its level of saturated fat. Second, consumers can have knowledge about how the benefits of these attributes—how these nutritional properties—affect one's health. The understanding that a diet low in saturated fat can help prevent heart disease or that a diet high in vitamin A helps vision are both examples of this second type of knowledge.

When both of these types of knowledge—attributes and benefits—are jointly present, a much higher level of understanding occurs than if a consumer knows one but not the other. Having knowledge of both nutritional attributes and health benefits has been correlated with an increased consumption of both soy foods (Wansink and Chan 2001) and functional foods (Wansink, Westgren, and Cheney 2005).

The placement and wording of FDA health claims are designed to inform consumers of this important connection between diet and health. When consumers lack important nutritional background, however, they can be reluctant to believe this connection between diet and health. It is important for consumers to know the nutritional quality of food and how certain nutritional aspects affect health. If an FDA health claim is to be successful in increasing the consumption of a particular food, the people evaluating the health claim must be able to make this important connection between diet and health.

WHAT WE CAN LEARN FROM THE PAST

The currently approved FDA health claims have been met with mixed success in terms of their goal of informing consumers about the health benefits of particular products and encouraging consumers to eat those products (Wansink 2005). By examining these approved FDA health claims, evidence can be collected and generalizations made as to what helped the claims become effective or ineffective and what can be learned about the relative success or failure each health claim had in persuading consumers. The following groupings of health claims help to provide a general framework for analyzing the reasons behind the successes and failures.

Claims That Target a Specific Population Segment

Health claims that target a specific population can be tremendously successful in building a diet–health relationship between a particular health benefit and a particular food in the mind of consumers. For example, consider the FDA health claim about calcium and osteoporosis that stated “regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.” This health claim successfully creates diet–health relationship in the minds of consumers by drawing upon a long history of nutritional education about the health benefits of calcium and directly connecting that knowledge to a set of food products that are either traditionally associated with calcium (such as milk) or are explicitly labeled as being fortified with calcium. Since the beneficiaries of calcium are generally a well-defined segment of the population—the very young and the very old—this claim was able to specifically and successfully target the relevant target segments.

Despite the relevance of targeting a health claim at a particular consumer segment, without a base of preexisting nutritional knowledge about the health benefits of a particular nutrient, the success of a health claim is compromised. For example, consider the claim that examines the links between folic acid and neural tube birth defects. It informs consumers that “Healthful diets with adequate folate may reduce a woman’s risk of having a child with a brain or spinal cord birth defect.” Although this claim is specific to pregnant mothers, there is little awareness of either the general health benefits of folic acid or the foods that contain folic acid (despite folic acid’s wide availability in cereals, legumes, peas, fresh leafy green vegetables, oranges, grapefruits, and many berries). As a result, this claim was not able to establish a diet–health relationship in the minds of consumers, and it did little to boost sales of foods that contain folic acid.

Claims That Received Significant Media Attention

Having a health claim receive significant media attention can be instrumental to informing consumers of both the health benefits to a particular nutrient and the types of foods in which that nutrient is found. Consider the FDA health claim relating to fat and cancer (“Development of cancer depends on many factors. A diet low in fat may reduce the risk of some cancers.”) and the claim relating to saturated fat and cholesterol/heart disease (“While many factors affect heart disease, diets low in saturated fat

and cholesterol may reduce the risk of this disease.”). The significant media attention that the claims received in the late 1990s contributed to their overall success in increasing sales of low-fat foods like fruits, vegetables, reduced fat milk products, cereals, pastas, flours, whole grain, and sherbets. Because media outlets widely reported the health claims, consumers became aware that fat and saturated fat influenced their health. The media attention augmented and amplified a consumer’s diet–health relationship awareness and helped decrease the consumption of high-fat products.

Claims That Were Promoted by Companies

Companies can also take the lead in providing consumers with nutritional information to help support a health claim and increase sales of products that carry that claim. Consider the cases of the health claims regarding fiber and cancer (“Diets low in fat and high in fiber containing grain products, fruits, and vegetables may reduce the risk of some cancers.”), fiber and heart disease (“Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.”), and soluble fiber and heart disease (“Diets low in saturated fat and cholesterol that include soluble fiber may reduce the risk of heart disease.”). Although there was some general consumer awareness about the nutritional benefits of fiber because of the Food Pyramid program, the link between high-fiber diets and good health was strengthened by proactive campaigns from companies such as Quaker Oats and Kellogg, which informed consumers about the benefits of fiber and the presence of fiber in their cereals. In one instance, the National Cancer Institute lent its credibility and objectivity to an educational campaign conducted by Kellogg Company. Both consumer awareness of fiber in the foods they buy and the awareness of the health benefits to fiber made these two health claims successful.

It is important to build public awareness of a particular nutrient and its effect on health if a health claim is to be successful. As the case of the health claim for plant stanol (“Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease.”) demonstrates that if consumers are unaware of the benefits of a particular nutrient (in this case, plant stanol esters), the health claim is simply going to be ignored and the effect on sales will be minimal.

Claims That Highlight Quantitatively Measured Health Benefits

Health claims can be successful when they relate to health information and health benefits that are quantifiable and easily observable. For example, the FDA health claim on the link between sodium and high blood pressure (“Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.”) became successful because consumers could easily read the sodium contents on the foods they consumed. When products that have low sodium content such as unsalted tuna, salmon, fruits, vegetables, low-fat milk, low-fat yogurts, cottage cheese, cereal, flour, and pasta were considered in light of the health claim, consumers were influenced to consume those products because they could also quantitatively measure the benefits through lower blood pressure. The diet–health relationship between high sodium content and high blood pressure was easy to successfully establish.

Claims That Become Personal

Many consumers have a vivid connection with serious health problems such as cancer or heart disease. In some cases, this can be through personal experience with the disease, or with family members or friends who have suffered from it. A health claim that offers to help lower the risk of such personally experienced diseases can become vivid and successful because of this personal connection. For example, the health claim relating to fruits and vegetables to cancer (“Low-fat diets rich in fruits and vegetables [foods that are low in fat and may contain dietary fiber, vitamin A, or Vitamin C] may reduce the risk of some types of cancer, a disease associated with many factors.”) offers a strong diet–health connection between eating fruits and vegetables and lowering the risk of the personal recognized problems of cancer.

There may be some reason to believe that this personal experience can work against the success of a claim when the health benefits being promoted are minor and relatively inconsequential. For example, the recent health claim about sugar and tooth decay (“Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.”) does not have the gravity of cancer. Although most people recognize the importance of dental hygiene and the effects of sugar on tooth decay are widely known, the personal experience consumers have with tooth decay shows the problem to be manageable. It does not necessarily provide them with a sufficient reason to consume a particular product carrying the tooth decay health claim.

Table 1 provides a summary of points relating to each of the health claims and what contributed to their success or failure. It also provides general lessons that can be used to help with future health claims in the United States or abroad.

IMPLICATIONS

Food labels can be important in helping consumers recognize that a product contains a particular nutrient, particularly when used in combination with consumer education, advertising, and public relations efforts (Caswell and Padberg 1992). Aside from nutritional content, food labels also help

TABLE 1
Principles of Health Claim Leveraging Success

Principle	Benefits	Examples
Claim targets a specific segment of the population	Makes claim more believable	Calcium's claim targeted the very young and the very old
Claim has received significant media attention	Draws the attention of targeted consumer groups	Folic acid's claim targeted pregnant mothers
	Informs broad-range consumers about the relationship between a certain nutrient and health Makes the claim more believable and authentic	Fat and saturated fat health claims linked low-fat diets with decreased risk of cancer
Claim is introduced along with an aggressive proactive marketing campaign	More persuasively and professionally informs consumers of a nutrient's health benefit Links this health benefit to specific foods in a memorable manner	Quaker Oats' and Kellogg's marketing campaigns highlighted the link between fiber and a low risk of heart disease
Claim highlights quantitative health benefits	Allows consumers to specifically see the benefits of altering their diet Increases believability when early-adopting consumers report their results	Sodium's health claim linked a diet low in sodium to a low blood pressure number
Claim helps prevent a vivid, personally relevant health problem	Makes health claim more believable and realistic Increases awareness of the risks associated with diets lacking beneficial nutrient	Heart disease's health claim linked diets rich in fruits and vegetables to a decreased risk of cancer

signal product quality, consumer knowledge, purchasing patterns, and usage patterns (Caswell 1992; Caswell and Mojdzuska 1996). It must be realized, however, that in the absence of supporting, integrated communication efforts, labeling alone is not always persuasive. Many consumers do not look at the nutritional information on a product label, and others do not understand or believe it. When creating a nutritional label that will both be recognized and believed, special attention should be placed upon whether consumers will notice, understand, believe, and respond to it. Recent work is beginning to show that combining short health claims on the front of a package with full health claims on the back of the package leads consumers to more fully process and believe the claim (Wansink, Sonka, and Hasler 2005). The basic finding that using two sides of a package (short claim on front; long on back) increases the believability of health claims is relevant for policy makers, consumers, and researchers (Wansink 2003).

Long-term behavioral change can only be achieved through a cohesive communication, education, and marketing effort. Nutritional and promotional messages should work in conjunction with food developers and package designers to create a system of labeling (coupled with education) to alert consumers of the nutritional contents of a particular product.

When consumers believe a health claim is accurate because it appears on the food label, this belief is often predicated upon both a strong awareness of a certain nutrient in a food and an awareness of that nutrient's effect on health. In cases where health claims are not understood or believed, often it is a breakdown in these two types of awareness that leads to the confusion or disbelief. This should remind dietetic practitioners of their continual role in providing and ensuring accurate nutrition education for the public (Fullmer, Geiger, and Parent 1991). This foundation can facilitate their understanding and acceptance of FDA health claims.

The success of FDA claims is greatly facilitated by nutritional campaigns that previously laid the groundwork of basic nutrition information. Whereas many nutrition education efforts have been ineffective (Wansink 2002), effective efforts have taken a marketing-related approach toward education. That is, they have used a strong consumer orientation, segmented and targeted specific consumer groups, and used multiple communication channels, and they continually refined the message and its benefit proposition.

To help facilitate these educational campaigns, strategic partnerships can help promote changes in behavior. Such partnerships provide the credibility, competency, and skills that government agencies or industry may lack on their own. Organizations such as the National Cancer Institute and American Medical Association should be considered primary targets for partnerships. In fact, partnerships can help design and conduct the

clinical trials necessary to conclusively demonstrate the delivery of health benefits through a particular product, which is essential for a successful product to be sold for its health benefits (Witwer 1999). As a result of the dissemination of information from those clinical trials, consumers will be able to recognize the health benefits that derive from certain nutrients in food.

Implications for Soy Health Claims: A Brief Case Study

To illustrate these implications, consider the health claim detailing the link between soy protein and heart disease. Soy is an interesting case study because the health benefits of consuming it are often overshadowed by perceptions of it having an unfavorable taste (Wansink and Park 2001). Although this is not a unique situation—it was also the case when encouraging people to eat organ meats during the rationing years of World War II (Wansink 2002)—it makes it much more difficult for an FDA claim to influence behavior. In such cases, two general education strategies could be considered and supplemented with well-executed “Five P” marketing tactics (Pricing, Promotion, Placement, Product, and Packaging).

Adding a New Salient Health Belief

Most consumers’ primary association with soy is that “It tastes bad.” By adding a more salient health-related belief—such as its ability to reduce the risk of heart disease—it may be possible to overshadow their initial taste-related resistance. Adding such a benefit may have a greater effect on the individual than trying to directly address their bias against its unfavorable taste. It is possible to influence consumers to see this utilitarian benefit as the most salient related to the food.

Making an Existing Belief More Salient and Consequential

It is critical to enhance the salience of this health-related belief. This can be done by promoting the benefits of eating healthy and thus inducing consumers to place this attribute as a primary criterion to use when considering a food purchase. This implies focusing even further on the claim-related benefits of eating healthy (e.g., feeling energetic). By doing so, it will be more possible to induce consumers to place higher emphasis on motivators such as the health issues. Again, the emphasis is on making an existing belief more salient and more consequential to their everyday life.

TABLE 2
Leveraging the Health Benefits of a Claim-Related Ingredient: The Case of Soy

Context of Use	Guidelines	Rationale and Illustrations
Education	Design clinical studies for health professionals	Exhibits advantages to professionals, supplies them with products and ideas about how to educate their patients
	Implement social marketing campaigns	Provides favorable publicity for firm that develops social campaigns
	Educate consumers on preparation ease of soy	Provides recipes and where to find products
	Develop education programs for nutrition educators on how to target and how to change the motivations of potential consumers	
Promotion	Use Five-A-Day program	"Soy is a vital part of your Five-A-Day program"
	Copromote with Heart and Cancer Associations	"The AHA recommends 20 grams of soy a day. This product contains 100% of daily recommendations"
	Use Point-of-Purchase reminders of health benefits	
Packaging	Use words that can be easily quantified	Use words such as less, more, reduced; also, use percentages and quantities
	Keep front-label information simple and link to nutrition panel for credibility	Use words such as "Packed with Soy Protein"
	Include readily identifiable symbols of affiliation	Have the Healthy Heart check and the American Cancer Association symbols easily visible. Include a soy symbol alongside to build awareness and credibility
Placement	Distribute through health food stores	Avoid placement in special "health food" section of the grocery store (focus on general public instead)
	Stock shelves next to comparable products in grocery stores	Place in other outlets where the fact that the product is there implies its health benefits
	Consider leaving samples or information in doctor's offices, health-care offices, or gyms	
Product	Fortify existing products	Add soy to the diets of people who would not necessarily purchase soy products
	Expand product lines through line extensions	Give existing products a soy line as an option
Pricing	Price premium products at a higher price point	Do not price low if it may give soy a "cheap" image so when people become more affluent
	Price introductory products lower than competing products to encourage adoption	Emphasize price and health benefit combination (eat healthy for the same price)

As Table 2 illustrates, the consumer acceptance of particular health claims requires efforts in the areas of education, promotion, packaging, product placement, product development, and pricing. No single method will work in all cases; instead, care must be taken by policy makers to develop a diverse multipronged approach. The focus should be on laying a concrete groundwork of nutritional education information that can be later leveraged by more direct marketing strategies to establish a clear diet–health relationship in the mind of consumers, therefore increasing consumption of particular healthy foods (Wansink et al. 2005).

SUMMARY

FDA health claims can influence consumer behavior best when two conditions exist. First, the consumer must be made aware that the product carrying the health claim possesses the target nutrient. Second, the consumer must be made aware that the target nutrient provides a health benefit that is personally relevant to them. A combination of these two factors establishes—in the consumer’s mind—a clear diet–health relationship between a particular product and a particular health benefit that is personally relevant to them. This can motivate that consumer to consume that particular product. Although all products that establish a diet–health relationship have the potential to influence consumer behavior, it takes an extra level of motivation to translate that potential into action (consumption). Past health claims provide clear examples of key principles, which can be made to leverage health claims and make them more successful. Future health claims, as illustrated with the soy health claim, should capitalize and build upon the lessons of the FDA health claims discussed here to successfully leverage their claim to increase product consumption.

REFERENCES

- Bender, Mary M. and Brenda M. Derby. 1992. Prevalence of Reading Nutrition Information and Ingredient Information on Food Labels among Adult Americans: 1982–1988. *Journal of Nutrition Education*, 24 (6): 292–297.
- Blaylock, James, Smallwood David, Kassel Kathleen, Variyam Jay, and Lorna Aldrich. 1999. Economics, Food Choices, and Nutrition. *Food Policy*, 24: 269–286.
- Caswell, Julie A. 1992. Current Information Levels on Food Labels. *American Journal of Agricultural Economics*, 74: 1196–1201.
- Caswell, Julie A. and Eliza M. Mojduszka. 1996. Using Informational Labeling to Influence the Market for Quality in Food Products *American Journal of Agricultural Economics*, 78: 1248–1253.
- Caswell, Julie A. and Daniel I. Padberg. 1992. Toward a More Comprehensive Theory of Food Labels. *American Journal of Agricultural Economics*, 74: 460–468.

- Federal Register*. 1993. Food Labeling: General Requirements for Health Claims for Food. 58: 2478–2536.
- Feick, Lawrence F., Robert O. Herrmann, and Rex H. Warland. 1986. Search for Nutrition Information: A Probit Analysis of the Use of Different Information Sources. *Journal of Consumer Affairs*, 20 (2): 173–192.
- Food and Drug Administration (FDA). *Health Claim Citations*. <http://www.cfsan.fda.gov/~dms/lab-ssa.html>.
- Ford, Gary T., Darlene B. Smith, and John W. Swasy. 1990. Consumer Skepticism of Advertising Claims: Testing Hypotheses from Economics of Information. *Journal of Consumer Research*, 16 (March): 433–441.
- Fullmer, Susan, Constance J. Geiger, and C. R. Michael Parent. 1991. Consumers' Knowledge, Understanding, and Attitudes toward Health Claims on Food Labels. *Journal of the American Dietetic Association*, 91 (2): 166–171.
- Hurt, David H. and Stephanie C. Crocco. 1986. Dietary Fiber: Marketing Implications. *Food Technology* (February): 124–126.
- Ippolito, Pauline M. and Alan D. Mathios. 1991. Health Claims in Food Marketing: Evidence on Knowledge and Behavior in the Cereal Market. *Journal of Public Policy & Marketing*, 10: 15–32.
- Levy, Alan S. 1995. *PHS Food Label Health Claims Focus Group Report: Executive Summary*. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Market Studies.
- McMahon, Kathleen. 1996. Will Pending Health Claims Regulations Motivate Consumers to Change Dietary Practices? *Journal of Nutrition Education*, 28 (5): 254–256.
- Porter, Donna, Penny Kris-Etherton, Susan Borra, Mary Christ-Erwin, Porter Novelli, John Foreyt, Jeanne Goldberg, Lyn O'Brien Nabors, Nancy Schwartz, Christine Lewis, William Layden, and Christina Economos. 1998. Educating Consumers Regarding Choice for Fat Reduction. *Nutrition Reviews*, 56 (5): S75–S100.
- Silverglade, Bruce A. 1991. A Comment on "Public Policy Issues in Health Claims for Foods." *Journal of Public Policy & Marketing*, 10: 54–62.
- Szykman, Lisa R., Paul N. Bloom, and Alan S. Levy. 1997. A Proposed Model of the Use of Package Claims and Nutrition. *Journal of Public Policy & Marketing*, 16 (2): 228–241.
- Wansink, Brian. 2002. Changing Eating Habits on the Home Front: Lost Lessons from World War II Research. *Journal of Public Policy & Marketing*, 21 (1): 90–99.
- . 2003. How Do Front and Back Package Labels Influence Beliefs about Health Claims? *Journal of Consumer Affairs*, 37 (2): 305–316.
- . 2005. *Marketing Nutrition: Soy, Functional Foods, Biotechnology, and Obesity*. Champaign: University of Illinois Press.
- Wansink, Brian and Nina Chan. 2001. Relation of Soy Consumption to Nutritional Knowledge. *Journal of Medicinal Foods*, 4 (3): 147–152.
- Wansink, Brian and Se-Bum Park. 2002. Sensory Suggestiveness and Labeling: Do Soy Labels Bias Taste? *Journal of Sensory Studies*, 17 (5): 483–491.
- Wansink, Brian, Steven Sonka, Peter Goldsmith, Jorge Chiriboga, and Nilgün Eren. 2005. Increasing the Acceptance of Soy-Based Foods. *Journal of International Food and Agribusiness Marketing*, 16 (1): forthcoming.
- Wansink, Brian, Steven T. Sonka, and Clare M. Hasler. 2005. Front-Label Health Claims: When Less Is More. *Food Policy*, forthcoming.
- Wansink, Brian, Randall E. Westgren, and Matthew M. Cheney. 2005. The Hierarchy of Nutritional Knowledge That Relates to the Consumption of a Functional Food. *Nutrition*, forthcoming.
- Witwer, R. Scott. 1999. Marketing Bioactive Ingredients in Food Products. *Food Technology*, 53 (April): 50–53.

APPENDIX

FDA Approval Process

Obtaining FDA approval for a health claim must meet the following requirements:

1. The food must meet specific nutrient criteria for each health claim (e.g., 20% daily value for calcium to make the calcium and osteoporosis claim).
2. The food must not exceed disqualifying levels for nutrients that are of public health concern (e.g., fat [greater than or equal to] 13g, saturated fat [greater than or equal to] 4g, cholesterol [greater than or equal to] 60mg, and sodium [greater than or equal to] 480 mg).
3. The food must be a “good source” (e.g., contain [greater than or equal to] 10% daily value for at least one of the following nutrients, without fortification; vitamin A, vitamin C, iron, calcium, protein, or fiber).

In order for the FDA to approve any health claim that meets the previous requirements, the petitioner must also supply information that meets the following regulations:

- The claim must originate from a federal scientific body (e.g., the National Institutes of Health, National Centers for Disease Control and Prevention, U.S. Department of Agriculture, or National Academy of Sciences).
- The claim must be published by the scientific body and be currently in effect.
- The claim must state a relationship between a nutrient and a disease or health-related condition.
- The claim must not be a statement made individually by an employee of a scientific body but rather reflect a consensus within the scientific body.
- The claim must be based on the scientific body’s deliberative review of the scientific evidence.

The FDA also allows for another type of health claim called a structure–function claim. In this claim, a product may claim that a particular ingredient supports a certain health function (i.e., lecithin can improve brain development and isoflavone intake may help women avoid the bone loss). Structure–function claims are intermediate-level claims that can be approved if there is not yet sufficient research to prove a health claim.