

Claiming a Function

Foods with functional benefits have emerged as a key market for manufacturers in recent years, as time-struggling yet health-conscious consumers seek a quick, convenient means to maintain their overall health. Functional foods would seem to fit the bill perfectly; however, manufacturers be warned: consumers may not embrace claim-touting new products.

William A. Roberts, Jr., Business Editor

The FDA permits health claims on foods, with the goal of alerting consumers to a product's potential health benefits. Items bearing such a claim may, as part of an overall healthful diet plan, reduce the risk or control the effects of some diseases; however, the claims are not to imply that such foods serve as a cure for any specific disease. The intent is to guide consumers who attempt to use their diet to reduce the risk of disease or to prevent exacerbating a current health condition.

A report by Datamonitor notes the sales of such functional products in the U.S. hit \$18.9 billion in 2004, and annual sales growth has averaged 7.2% between 1999 and 2004. Other analyses come up with different totals, perhaps due in part to how they define the category.

In "FDA-approved Food Health Claims," a report released in November of 2005, Mintel International makes a larger estimate of the total market for products with a healthful purpose: "The market size of the selected foods that can leverage the FDA labeling was \$39.2 billion in 2005." The total U.S. retail sales of these food items have increased 6% at current prices (a 6% decline at constant 2005 prices) from 2000 to 2005. Mintel believes that trend will continue through 2010, predicting a 12% increase at current prices, a 5% decline in constant prices over that time. A number of possible reasons are to blame for the constant price decline, but further complicating matters are the diet trends and fads of

The functional benefits of Kashi's Heart to Heart instant oatmeal are touted proudly on the front of the box, informing consumers they can "Reduce Cholesterol...Support Healthy Arteries...(and) Manage Hypertension."

recent years, which have contributed to constant-dollar drops in most segments. It is worth noting that Mintel's report focuses only on products with FDA qualified health claims; any mention of health claims in the context of Mintel's report refers to FDA qualified claims.

As Mintel notes, "Prior to a change in the authorization process [which allowed for qualified health claims], 14 key [unqualified health] claims had been permitted. Since July 2003, a further four claims have been authorized." At the time of the report, another dozen products or ingredients were awaiting authorization. That change in the authorization process likely will lead to quicker agreement on permitted claims than was the case prior to 2003. Therefore, Mintel suspects "the number of foods eligible to bear FDA health claims is likely to increase."

The relaxed guidelines for health claim labeling resulted from concerns about violating manufacturers' First Amendment rights, asserts Mintel. Currently, three levels of qualified health claims (FDA categories B, C and D) are allowed by FDA:



■ Category B claims must state, "Although there is scientific evidence to support (the claim being made by the manufacturer), the evidence is not conclusive."

■ Category C must note, "Some scientific evidence suggests that (claim being made by the manufacturer); however, FDA has determined that this evidence is limited and not conclusive."

■ Category D claims have to declare, "Very limited and preliminary scientific research suggests (the claim being made by the manufacturer). FDA concludes there is little scientific evidence to support this claim."

"The correlation between diet and health can be seen in the fact that all of the illnesses for which the FDA provides health claims can be treated with a combination of medication and diet, and some can be controlled by diet alone," Mintel notes. Interestingly, almost all of the diseases addressed by the claims affect Baby Boomers which, by coincidence, is a demographic known for its proactive stance on health, diet and nutrition.

Wary Consumers

By and large, however, consumers are wary of health messages. HealthFocus International research shows consumers placing less weight on health claims than in the past: in a 1998 survey, 46% of U.S. respondents regarded health claims as extremely or very important; in 2004, the last year for which results are available, that number had

Staking a Claim

Before July 2003, 14 specific health claims were permitted by the FDA, centered on the relationships between the following:

- Calcium and osteoporosis
- Sodium and hypertension
- Dietary fat and cancer
- Dietary saturated fat and cholesterol and risk of coronary heart disease
- Fiber-containing grain products, fruits, and vegetables and cancer
- Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease
- Fruits and vegetables and cancer
- Folate and neural tube defects
- Dietary sugar alcohol and dental caries
- Soluble fiber from certain foods and the risk of coronary heart disease
- Soy protein and risk of coronary heart disease
- Plant sterol/stanol esters and risk of coronary heart disease
- Whole-grain foods and risk of heart disease and certain cancers, and
- Potassium and the risk of high blood pressure and stroke.

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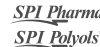


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dropped to 38% of respondents. The reason for that wariness may be due to the FDA itself.

The FDA's changes in health claim regulations could be leading to some skepticism. The FDA and the International Food Information Council (IFIC) performed a survey between 2003 and 2004. Published in 2005, it found consumers were confused about the merits of the new health claim labeling guidelines. Specifically, consumers were not able to determine how much scientific evidence supported each tier of claims, nor could they ascertain the extent to which a product or ingredient could be truly beneficial.

In another survey, Datamonitor's recent look at the functional foods market found nearly 50% of consumers regard manufacturers' claims untrustworthy. (It is worth noting that manufacturers are not permitted to make health claims not approved by the FDA.) Some 45% of Americans say they largely or entirely disbelieve food and drink manufacturers' health claims, a figure similar to the distrust found in France and far more than seen in the Netherlands.

Mintel's report on FDA claims notes that women are more likely than men to be aware of the relationship between food and health. Furthermore, because they do the majority of food shopping in most households, women tend to be more aware of health-related food labeling. With recent media coverage of life-threatening heart disease, food manufacturers have focused efforts on campaigns to increase awareness of heart disease among women.

A separate Mintel report, "Soy Food and Drink, U.S.," released in June of this year, explains a bit of the history of soy and heart health. The mid-1990s saw soy first hit the market with a number of health claims. Consumers embraced the products for a couple of reasons: possible cancer prevention, and as a replacement for estrogen therapy for women dealing with symptoms of menopause. However, the market for such soy products has waned: "The lack of FDA-approved health claims for soy as a cancer preventative or an estrogen replacement has been part of the reason that sales of these products have stagnated," notes that Mintel report.

Having Heart

The FDA permits one health claim for soy, and it relates to heart health. Considering 70 million Americans have some form of heart disease, that opens a fairly large market. A Mintel poll (see chart "Say Say Soy") found the top two reasons for purchasing soy products are health-related, and the research group



Lifeway Foods' Kefir range of probiotic organic smoothies claim to aid in digestion, as well as strengthen the immune system.

advises, "The health benefits of soy endorsed by the FDA should be points of departure for campaigns designed to attract more consumers to these products."

One issue may be that companies are inconsistent about using a claim to market their products. At the time of the report, neither Boca Burger's or Gardenburger's websites mentioned the link between heart health and soy, and a cursory look at both sites recently showed that still is the case. Meanwhile, 8th Continent soymilk has made a point of emphasizing heart health on its website and mentions the "red dress campaign" for women's heart health on all of its packaging. Silk brand soymilk features information about its products and heart health; however, it leans toward environmental rather than health issues. Furthermore, for the

most part, soy bars aimed at women (including Luna and Pria) promote overall women's wellness but make no specific mention of the heart-healthy aspects of soy in any major way. Mintel's soy foods report believes manufacturers are allowing prime opportunities to pass, as cardiovascular disease is a serious threat to men

Functioning Well

U.S. Retail Sales of FDA-approved Food, in Millions

Year	Sales (Current Prices)	% Change	Sales (Constant 2005 Prices)	% Change
2005 (est.)	\$39,208	1.3%	\$39,208	-1.6%
2004	\$38,692	3.8%	\$39,853	1.1%
2003	\$37,284	0.8%	\$39,425	-1.5%
2002	\$36,993	-1.4%	\$40,009	-3.0%
2001	\$37,537	1.7%	\$41,239	-1.1%
2000	\$36,900	—	\$41,693	—

Source: Mintel, based on Information Resources Inc. Infoscan Reviews Information/SPINS



Take Control is made with a natural soybean extract that claims to be proven to lower cholesterol significantly when part of a diet low in saturated fat and cholesterol.

some of the diseases and conditions pertain more (or exclusively) to women than to men, but it is also the case that women are more likely, as noted, to be aware of the relationship between diet and health. Overall, six in 10 respondents say they find printed health claims on food packaging helpful when deciding which products to purchase. More than nine in 10 of the respondents say they “associate specific foods with specific health functions, even if those relationships are not currently sanctioned by the FDA,” says Mintel, and female respondents are somewhat more likely than males to do so.

and women, and continues to increase as obesity rates increase and Boomers age.

That sentiment is echoed in Mintel’s report on foods with FDA health claims: “The aging Baby Boom generation will continue to seek food that will help them grow old healthfully and provide them with the sense that they are doing all they can to prevent or stave off the effects of certain diseases. High cholesterol, heart disease, osteoporosis and stroke are all illnesses associated with old age, and Boomers are well aware of both the causes and the prevention of many of these conditions. Many believe in looking for foods that will help them stay healthy, and they will continue to look for information on how to prevent illness.” That is not to say Boomers are the only potential market for foods with a function; Datamonitor’s examination of the global functional food market found young European adults consume 36% more nutraceuticals than the average consumer, and 28% of young U.S. adults do so.

Exclusive consumer research cited in the Mintel report shows respondents are aware of the link between diet and health. More than two thirds look for foods that help or prevent a range of ailments and conditions, be it high cholesterol, birth defects or heart disease. The major claims most likely to lure consumers are related to heart health: high cholesterol and heart disease.

Not surprisingly, male respondents are not as likely to seek foods to help or prevent certain conditions or diseases: some 60% of male respondents versus 76% of female respondents. Granted,

Cutting Claims

The list Mintel put forth to its survey respondents included some health claims not permitted by the FDA, suggesting consumers are getting information from sources other than approved package labeling. With a surge in FDA qualified health claims, some analysts have pondered whether consumers will value the ever-growing number of “good-for-you” foods. Even some consumer groups worry that the result will be a glut of such food items, with “spurious claims to vague health benefits,” to quote Mintel’s “FDA-approved Food Health Claims” report. The California Milk Processing Board (CMPB), for instance, decided to stop using the calcium and milk claim connection for advertising, concluding the calcium claim had, in effect, been overused to the extent that consumers no longer regarded it as useful information for making an informed dietary decision.

Such a concern would seem valid in light of HealthFocus’ survey. It found the percentage of consumers

who ranked the following claims as being extremely or very important declined five percentage points between 1998 and 2004: “helps to build strong bones,” “supports the immune system,” “helps to maintain healthy cholesterol levels” and “may reduce the risk of cancer.” Furthermore, there was a four-point drop in the respondents who regarded “may help to prevent osteoporosis” as extremely or very important; consumer opinions of “may reduce the risk of heart disease” dipped one percentage point during the same time frame.

Say Say Soy

Reasons for Purchasing Soy Products

They should be part of a healthy diet	48%
Heart health	39%
To avoid dairy products	27%
To reduce the amount of meat in the diet	27%
Vegetarian or vegan	10%
Menopausal aid	7%
Other	19%

Source: Mintel
n=415 adults who bought soy-based versions of popular food and drink in the past 12 months

The new health claims have many consumers concerned for a variety of reasons, which Mintel addresses in the FDA claims report. One example is the worry that the D category of qualified statements may be too vague and could be exploited with a proliferation of products that truly are not healthful. Mintel further cautions, "...the new labeling may permit companies to label packaged products as 'healthy' because they contain one ingredient that has been given such a label by the FDA, even if other ingredients are not healthful at all." Mintel hypothesizes that "a manufacturer could label a...high-fat and high-calorie product as 'heart-healthy' if it also contained one 'heart-healthy ingredient' along with the other unhealthy ingredients." The FDA does try to prevent this by often requiring that a food meet a number of other criteria for health. For example, one government website notes that if a food wants to make the heart health claim for soluble fiber—"Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease—21 CFR 101.81"—it also must be "low saturated fat," "low cholesterol" and "low fat" (see "Website Resources").

Mintel's report is not overly optimistic about the future of the D claim, noting "some question whether or not the D ranking will remain." The reason is a simple one: the foods with this claim do not seem to have enough scientific support to convince consumers. Manufacturers, meanwhile, seem upbeat about the new claim-labeling regulations, particularly those covering B and C claims, according to Mintel. They believe these will lead to more foods that can be tied to health; these would be items with qualified claims so that consumers may choose the best foods for their current health conditions and for their desired health conditions in the future.

The FDA/IFIC survey demonstrated consumer confusion about the merits of the new qualified health claim labeling guidelines. Consumers, Mintel asserts, might prefer simpler language relating food to health, as seen in structure-function claims and dietary guidance statements. Nonetheless, Mintel's exclusive consumer research indicates some opportunity for manufacturers. Simply put, consumers do associate certain foods with healthful benefits. Some 82% of respondents related vitamin C with immune support, while 78% noted the bladder-health benefits of cran-

berries. The cancer-preventive aspects of antioxidants were recognized by 63%, while 61% equated garlic with heart health, well above the 53% who associate omega-3 fatty acids with heart health.

Female respondents had a greater likelihood of believing the cancer-preventive benefits of antioxidants and vitamin E. Contributing at least in part to this increased awareness



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The Healthy Harvest line from New World Pasta claims to be a good source of fiber, whole grains and omega-3, not to mention its front-of-box American Heart Association endorsement.

among women has to be the emphasis on breast cancer awareness, prevention and cure. Men's cancers, meanwhile, have not received quite the same degree of media attention and, therefore, males are likely not as aware of the possibilities of certain foods as a means of cancer prevention.

Much like other diet patterns, humans are turning to functional items for their pets, and a number of makers of human supplements have joined the pets supplement arena, including items with multivitamins, probiotics and such functional ingredients as *Lactobacillus acidophilus*, *Lactobacillus casei*, *Streptococcus faecium*, *Saccharomyces cerevisiae*, *Aspergillus niger*, *Aspergillus oryzae* and *Bacillus subtilis*. A number of pet foods and treats that promote a healthy heart, skin, coat, eyes and metabolism are on the market. These include such seemingly human-centric ingredients as vitamin E and zinc.

Meeting Specs

Of the respondents in Mintel's research, more than nine in 10 associated specific foods with specific health functions, and it is worth noting that some of these consumer opinions

were for functional benefits not sanctioned at the time by the FDA. How did the consumers come to these opinions? Print and other media constantly report new scientific findings about the relationships between food and health, and healthcare professionals, friends and colleagues (not to mention the clerks at Whole Foods, etc.) are other sources of guidance. Regardless, as Marcia Mogelonsky, research analyst and author of a forthcoming Mintel report on the functional food market in the U.S., notes, it is clear that manufacturers will need to further educate the consumer about the specific health benefits of any functional ingredients. To do any less risks confusing the consumer, and a confused consumer is seldom a consuming consumer. **PF**

Much of this article is based upon information from a pair of Mintel reports—"FDA-approved Food Health Claims-November 2005" and "Soy Food and Drink-June 2006." Please visit <http://reports.mintel.com> for more information or call Mintel at 312-932-0400.

Website Resources:

www.mintel.com — Mintel International Group

www.NutraSolutions.com — Prepared Foods' special section devoted to the nutraceuticals market

www.cfsan.fda.gov/~dms/flg-6c.html — U.S. FDA Food Labeling Guide, Appendix C

www.eatright.com — American Dietetic Association (ADA)

www.americanutra.com — American Nutraceutical Association (ANA)

www.amsoy.org — American Soybean Association (ASA)

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