



Claims Crazy

WHICH CAN YOU BELIEVE?



Here's a quiz for the astute shopper: Which (one or more) of these claims can appear on a food or supplement label without approval from the Food and Drug Administration?

- (a) improves memory
- (b) relieves stress
- (c) suppresses appetite
- (d) helps reduce difficulty in falling asleep
- (e) supports the immune system

The answers: a, b, c, and e. They're called "structure/function claims," because they describe how a food or supplement affects the body's structure (say, the skeleton) or its function (for example, digestion). And manufacturers can slap one on virtually any food or supplement with or without evidence to back it up.

"The law says that structure/function claims can't be misleading, but the FDA has never said how much evidence a company needs to substantiate a claim," says Bruce Silverglade, director of legal affairs for the Center for Science in the Public Interest, publisher of *Nutrition Action Healthletter*.

Is one good study enough? What if that study is contradicted by a dozen others? "With no rules ensuring uniformity in structure/function claims, the resulting free-for-all could end up confusing consumers, and encouraging them to buy unhealthy foods," says Rep. Henry Waxman. The California Democrat is one of the strongest advocates of honest food labeling in Congress.

The FDA has no rules, in part because, until recently, structure/function claims only showed up on supplements.

No Approval Needed

In 1994, under strong industry pressure, Congress passed the Dietary

Supplement Health and Education Act. The law gives supplement-makers free rein to make structure/function claims, as long as the companies:

- notify the FDA within 30 days after using a new claim, and
- print the following disclaimer on the label:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

"Not evaluated" is right. "The FDA doesn't even look at the evidence behind structure/function claims," says

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A Fine Line

Which claims need FDA approval and which don't? When does a claim cross the line between offering to "affect the structure or function of the body" and promising to "prevent, treat, cure, mitigate, or diagnose" a disease? It's not easy to tell.

In January 2000, the FDA tried to answer that question, at least for claims on supplements. Here are some examples of claims that fall into each category.

No Prior Approval Needed (Structure/Function Claim)	Approval Needed (Disease Claim)
Helps maintain normal cholesterol levels	Lowers cholesterol
Maintains healthy lung function	Maintains healthy lung function in smokers
Provides relief of occasional constipation	Provides relief of chronic constipation
Suppresses appetite to aid weight loss	Suppresses appetite to treat obesity
Supports the immune system	Supports the body's antiviral capabilities
Relief of occasional heartburn or acid indigestion	Relief of persistent heartburn or acid indigestion
For relief of occasional sleeplessness	Helps reduce difficulty in falling asleep
Arouses sexual desire	Helps restore sexual vigor, potency, and performance

Other structure/function claims that need no prior approval

- Improves memory
- Improves strength
- Promotes digestion
- Boosts stamina
- For common symptoms of PMS
- For hot flashes
- Helps you relax
- Helps enhance muscle tone or size
- Relieves stress
- Helps promote urinary tract health
- Maintains intestinal flora
- For hair loss associated with aging
- Prevents wrinkles
- For relief of muscle pain after exercise
- To treat or prevent nocturnal leg muscle cramps

Silverglade. "It just makes sure that the supplement doesn't make a disease claim—one that's approved only for drugs."

According to the law, a disease claim promises to "diagnose, cure, mitigate, treat, or prevent disease." If a supplement makes a disease claim, then legally it becomes a drug. "Drugs must be pre-approved for safety and effectiveness, so that would make the supplement illegal," explains Silverglade.

But the distinction between a structure/function claim and a disease claim can be subtle. For example, "helps restore sexual vigor, potency, and performance" is a disease claim, says the FDA. In contrast, "arouses sexual desire" is a structure/function claim (see "A Fine Line," p. 3).

Got that?

"Studies show that consumers can't distinguish between disease claims and structure/function claims," says Silverglade.

And if shoppers can't, why should food companies bother with health claims when they can say just about anything they want by using structure/function claims?

Textbook Talk

"For years, the law has allowed structure/function claims on foods," explains Silverglade. "But companies rarely made them, probably because they didn't have much appeal."

The classic example was a statement like "calcium builds strong bones." "Structure/function claims were supposed to be something you might read in a textbook," says Silverglade.

Instead, the industry was fired up about health claims—that a food could, "as part of an overall diet," help reduce the risk of heart disease, cancer, or osteoporosis. In 1990, Congress passed a law permitting health claims, but with clear limits.

"The FDA had to approve the claim, and the food couldn't be too high in harmful nutrients like saturated fat or sodium or too low in vitamins and minerals," says Silverglade. "And the FDA could only approve the claim if it was backed by 'significant scientific agreement.'" In other words, the claim had to be supported by strong

and consistent evidence.

Since 1990, the FDA has approved 14 health claims (see "The 'A' List"). Apparently, that hasn't been enough for the food industry.

Tower of Babel

The Grocery Manufacturers of America, like other industry groups, has been hot under the collar over health claims for years.

The FDA approves claims "only where there is overwhelming science to support a diet/disease relationship, thus preventing the public from learning about new scientific developments until they have matured into hard science," a GMA spokesperson told Congress in May 2001. "As a result, the FDA has approved only a handful of disease/health claims...."

Not to worry, GMA. Last December, the FDA created a new kind of health claim. The agency announced that it would allow health claims for foods based on preliminary evidence as long as the label qualified it with a disclaimer like "this evidence is not conclusive."

These preliminary health claims haven't shown up on many foods yet. But even when they do, most companies will no doubt stick with anything

goes structure/function claims.

Why shouldn't they? Even preliminary health claims require approval and are prohibited on unhealthy or empty-calorie foods. What's more, structure/function claims have gotten jazzier. Goodbye, textbook. Hello, Madison Avenue.

"The supplement industry made a mint with structure/function claims," observes Silverglade. "Why should the food industry bother with health claims when they've got a free ride with structure/function claims? Food companies don't even have to notify the FDA or print a disclaimer, like supplement companies do."

Structure/function claims are starting to hit the marketplace...and no one's watching. So far, many are showing up on decent foods, like fruit juice and fruit (see "The Claim Game," p. 6). But it's only a matter of time before they start to pop up in the cookie, chip, and soft drink aisles.

Says Waxman: "The growth of structure/function claims for foods threatens to return us to the days when the Secretary of HHS called the food marketplace a 'Tower of Babel' for the consumer."



The Bottom Line

Here's how to tell one claim from another:

Solid Health Claims. These reliable claims—based on solid evidence—name a disease like cancer, stroke, or heart disease; usually refer to a "diet" that's low (or high) in some nutrient; and can't appear on unhealthy or empty-calorie foods.

Preliminary Health Claims. These unreliable claims are based on incomplete, shaky evidence. They have a disclaimer that ranges from the cautious ("the FDA has determined that this evidence is limited and not conclusive") to the silly ("the FDA concludes that there is little scientific evidence supporting this claim"). They can't appear on unhealthy or empty-calorie foods.

Structure/Function Claims. These unreliable claims require no approval—in practice, that may mean no evidence. Instead of diseases, look for words like "maintains," "supports," and "enhances" and euphemisms (like "optimizes bone health"). They can appear on any food.

THE A LIST

APPROVED HEALTH CLAIMS

Here are the 14 (slightly edited) health claims that the FDA has approved. Some are more popular than others. In fact, the claims without photos were so scarce that we had trouble finding them. Words in [square brackets] vary according to the food bearing the claim.



Diets rich in **whole grain foods** and other plant foods and low in total fat, saturated fat and cholesterol, may help reduce the risk of **heart disease** and certain **cancers**.



Diets containing foods that are good sources of **potassium** and low in **sodium** may reduce the risk of **high blood pressure** and **stroke**.

A diet low in **total fat** may reduce the risk of some **cancers**.



Three grams of soluble fiber from [oatmeal] daily in a diet low in saturated fat and cholesterol may reduce the risk of **heart disease**. This [cereal] has [two] grams per serving.



While many factors affect **heart disease**, diets low in **saturated fat** and **cholesterol** may reduce the risk of this disease.

Diets low in **sodium** may reduce the risk of **high blood pressure**.

Low fat diets rich in **fiber-containing grains, fruits, and vegetables** may reduce the risk of some types of **cancer**.



Diets low in saturated fat and cholesterol that include 25 grams of **soy protein** per day may reduce the risk of **heart disease**. One serving of this product provides at least [6.25 g] of soy protein.



Healthful diets with adequate **folate** may reduce a woman's risk of having a child with a **brain or spinal cord defect**.



Two or three servings per day with meals, providing 3.4 grams of **plant stanol esters** daily, added to a diet low in saturated fat and cholesterol may reduce the risk of **heart disease**. [Benecol Spread] contains [1.7 g] stanol esters per serving.

Diets low in saturated fat and cholesterol and rich in **fruits, vegetables, and grains** that contain some types of fiber, particularly **soluble fiber**, may reduce the risk of **heart disease**.



Does not promote **tooth decay**.

Low fat diets rich in **fruits and vegetables** containing **vitamin A, vitamin C, and fiber** may reduce the risk of some types of **cancer**.

The Claim Game

Through the Lutein Glass

Even someone with lousy vision couldn't miss the "New! With Lutein for Healthy Eyes" sign on Prune Juice+. Sunsweet has added enough lutein to supply 500 micrograms of the carotenoid per cup. Why?

"A growing body of scientific research links lutein consumption to a variety of eye health benefits, including a reduction in the incidence of macular degeneration, cataracts and retinal diseases," says the sign.

Sort of. In several studies, people who ate more lutein-rich foods had a lower risk of cataract surgery or degeneration of the retina's center (macula). And taking high doses of lutein (4,000 micrograms a day) raised the low levels of lutein in the retinas of patients with macular degeneration.

But no studies have tested whether lutein supplements reduce the risk of eye disease. That's why the National Eye Institute says that "claims made about an association between lutein and eye health are speculative and should be viewed with caution."

Cautious or not, it won't hurt you to get extra lutein in your prune juice. Just remember that Sunsweet is jumping to conclusions when it says that "lutein acts as nature's defense system for the eyes."



The Antioxidant Rag

Strawberry Kiwi V8 Splash is 75 percent sugar and water and only 25 percent juice—carrot, apple, kiwi, and strawberry. To boost Splash's nutrition credentials, the label declares that the beverage is "Rich in Vitamins A, C, E." (The C and E are added.) Unfortunately, its claims are misleading:

Vitamin A "is essential for vision and healthy skin." (People with severe vitamin A deficiency get skin lesions and go blind. But extra vitamin A won't do a thing for the average American's skin or sight.)

Vitamin C "is needed for healthy bones, gums and teeth." (Yes, people with scurvy—severe vitamin C deficiency—have bleeding gums and weak bones. But there's no evidence that extra vitamin C can help yours.)

Vitamin E helps "to protect cells from damage and promote a healthy immune system." (In theory, all antioxidants should protect cells, but studies that have tested vitamin E on people have found no drop in cancer or heart disease. And vitamin E may strengthen some immune functions, but no one has evidence that the vitamin prevents illness.)

You'll see A•C•E claims on many labels. Sounds good, but so far, no cigar.



So Proud

"Proud partners with the National Kidney Foundation," glows the label on Ocean Spray Cranberry Juice Cocktail. (You can choose your disease with Ocean Spray. Some bottles have the American Heart Association seal. Others are "proud sponsors of the American Diabetes Association." It's a very proud company.)

"This delicious juice drink is good for you because it helps maintain urinary tract health," say labels that feature the Kidney Foundation. Maybe.

Of the five best trials testing cranberry juice's ability to prevent urinary tract infections (UTIs), only two found that it worked.

"The small number of poor quality trials gives no reliable evidence of the effectiveness of cranberry juice and other cranberry products," concludes the Cochrane Collaboration, an international organization that rigorously reviews medical treatments.

And that won't change no matter how much money Ocean Spray gives the National Kidney Foundation.





Sneaky Del Monte

"High in Antioxidants," boasts the banner on the Del Monte Raisins box. To prove its point, the box shows the "Fruit Antioxidant Score" of prunes, raisins, blueberries, strawberries, and oranges. Raisins wouldn't have come in second, but third (well behind prunes and blueberries and barely above strawberries and oranges) if Del Monte had compared *one serving* of each fruit instead of *100 grams*—about 3½ ounces—of each. (A serving is a small box of raisins, an orange, or half a cup of berries.)

It's not clear what those antioxidants can do for you anyway. People who eat more fruits and vegetables have a lower risk of heart disease, stroke, and some cancers. But so far, studies that have given people antioxidants—like vitamin E or beta-carotene—haven't found any lower risk of heart disease or cancer.

Because raisins are low-fat, fiber-rich fruits, they qualify for the FDA-approved health claims on cancer and heart disease. But Del Monte implies that it's the antioxidant vitamins in raisins that lower the risk of those diseases...and "slow the effects of aging." Evidence? Who needs it?



Fruit Farce

Tropicana Twisters are only 10 to 15 percent juice. And despite names like "Mango Tangerine Mambo," the few spoonfuls of juice in each cup are mostly orange, grape, or apple.

Maybe that's why Tropicana needed "now with FruitForce energy releasing B vitamins!" to help sell its sugared water. B-vitamins help cells convert food to energy, but taking B-vitamins doesn't make you feel more energetic.

Want more B-vitamins? Take a multi-vitamin, not a 140-calorie glass of sugar, water, and 10 percent of a day's worth of niacin and pantothenic acid thrown in.



Total Trick

"Lose More Weight with 100% Daily Value of Calcium," promises Total's box. "As part of a reduced calorie diet," says the smaller print. (That always helps.)

"Now a recent study from a major university suggests that increasing calcium intake while cutting calories may help you lose more weight than dieting alone," explains the package. In fact, the evidence is flimsier than a wet Total flake.

Susan Barr, a researcher at the University of British Columbia, examined 17 clinical trials on calcium supplements and weight loss. "Only one study found greater weight loss in the supplemented group," she wrote. "In the remaining studies, changes in body weight and/or body fat were strikingly similar between groups."

The bottom line: "A recent study" could be the *only* one the company could find to back its claim.

Lycopene Lore

Campbell's Tomato Juice, Hunt's Whole Tomatoes, V8 Vegetable Juice, and others are suddenly talking about the "long-term health benefits" of "diets rich in tomatoes," which may be explained by lycopene, a "natural antioxidant."

While men who eat more lycopene-rich foods have a lower risk of prostate cancer, it's not clear that lycopene makes the difference. There's no harm in eating tomato foods. Just choose carefully. Campbell's Tomato Juice has 750 mg of sodium in each cup—too much to bear a health claim (see "The 'A' List," p. 5). But with structure/function claims like these, anything goes.