



FDA helps consumers get the whole story

Health claims about food products and dietary supplements may sometimes seem to contradict the latest information in an ad or article. The U.S. Food and Drug Administration is doing something about this, though new verbiage may require some serious reading between the lines.

QUESTION: What is new on food labels?

ANSWER: Food and supplement labels are now allowed to use "qualified health claims." Earlier, the FDA had approved health claims on foods and supplements only if the claim met the standard of "significant scientific agreement." This means the FDA must find that published scientific literature is *consistently* supportive of the claim. An example: "Adequate calcium intake throughout life helps maintain bone health and reduce the risk of osteoporosis."

Q: How do qualified health claims differ from unqualified?

A: Qualified health claims are those that do not meet the FDA's strict requirements for

"significant scientific agreement." Qualified claims must have some scientific basis, but don't need to meet the stringent requirements of unqualified claims. Qualified claims must also include statements intended to convey the extent of scientific uncertainty associated with the claim.

An example of a qualified claim for dietary supplements such as fish oils containing omega-3 fatty acids might read: "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive."

A claim approved for supplements containing a chemical (phosphatidylserine) extracted from soybeans must carry a stronger FDA qualification: "Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce

the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim."

Q: Why did the FDA develop this new procedure?

A: In December 2002, the FDA, along with the Federal Trade Commission and the National Institutes of Health, launched the Better Health Information for Better Nutrition initiative. Its goal is to provide consumers with more accurate health information.

As part of this initiative, the FDA and FTC increased the enforcement of laws protecting consumers from false and misleading claims. Two products recently associated with unsubstantiated claims are Bob Barefoot's coral calcium and Seasilver brand liquid supplement.

New qualified health claims may require more mental processing to get the point, but should increase awareness of what products are intended to do, while providing some perspective on how seriously to take the claim.

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