

That claim is authorized by FDA's "Letter Regarding Dietary Supplement Health Claim for Phosphatidylserine and Cognitive Dysfunction and Dementia," www.cfsan.fda.gov/~dms/ds-ltr33.html. That letter states that FDA will consider exercising enforcement discretion with respect to phosphatidylserine supplements that bear the above health claim (the first sentence) when the disclaimer (the second sentence) is placed immediately adjacent to and directly beneath the health claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. Phosphatidylserine supplements bearing the claim and disclaimer are required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims.

"Phosphatidylserine (PS) may reduce the risk of dementia in the elderly. Very limited and preliminary scientific research suggests that PS may reduce the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim."

That claim is authorized by FDA's "Letter Regarding Dietary Supplement Health Claim for Phosphatidylserine and Cognitive Dysfunction and Dementia," www.cfsan.fda.gov/~dms/ds-ltr33.html. That letter states that FDA will consider exercising enforcement discretion with respect to phosphatidylserine supplements that bear the above health claim (the first sentence) when the disclaimer (the second sentence) is placed immediately adjacent to and directly beneath the health claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. Phosphatidylserine supplements bearing the claim and disclaimer are required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims.

Additional claims, called "structure/function" claims, that refer to how a product affects a body structure or function without reference to a disease may be made if there is competent and reliable scientific evidence supporting the claims. Before making a claim of this kind, we ask that you send us the claim and the scientific evidence supporting it, and we will make a determination on whether we think the claim adequately supported and, thus, appropriate for use.

Advertising Regulations for American Longevity Products Amendment 2003



RULES AGAINST DECEPTIVE ADVERTISING

Federal law prohibits deceptive advertising, which includes both false and unsubstantiated advertising. You must not use false or misleading statements or material omissions of information that may deceive the public in any advertising. The Federal Trade Commission polices advertising media, including the internet, to identify and sanction those who engage in deceptive advertising. In recent years a very large number of dietary supplement companies and promoters have been prosecuted by FTC for deceptive advertising. To minimize the risk that any of our distributors will suffer that fate, we have developed the following strict rules. Please read them carefully. Complete compliance with them is not only expected, it is necessary to avoid running afoul of federal law. Please be mindful that under federal law AL is obliged to do whatever it can to prevent deceptive advertising by its distributors. Once on notice of deceptive promotions by an AL distributor, AL must and will act to avoid a federal law violation.

1. Web site links from distributor sites to any other are prohibited unless the other site in question has first been AL evaluated and approved for the link. AL will not approve any sites or content that contain health benefit claims for AL products or AL product ingredients unless the health benefit claims are approved by FDA or are scientifically validated structure/function claims.

2. AL requires pre-clearance of all distributor web sites. Moreover, it is a condition precedent to becoming a distributor and to continuing to serve as a distributor that each distributor execute a written certification confirming that, if the person has a web site, he or she has supplied it to AL for pre-clearance and will resupply it to AL for pre-clearance each time the site's content is changed. Receipt of the signed certifications will be a condition precedent to every new AL distributorship and to continuation of all existing AL distributorships.

3. AL conducts a comprehensive web search periodically, not less frequently than every six months. Any distributor found not in compliance with AL's prohibition against deceptive advertising will receive a warning letter by overnight mail. The letter will demand full compliance within 10 days of its date of issuance. A follow-up web search will then be conducted by AL on the 10 day anniversary of the date of warning letter issuance to determine whether all changes necessary to achieve full compliance have been made. Where it appears that no good faith efforts have been made to comply, AL will promptly (and without further notice) terminate the distributorship in question. Where it appears that good faith efforts have been made to comply but, in the opinion of AL, compliance is not achieved completely, AL will suspend the distributorship of the person in question until full compliance is achieved either through elimination of, or acceptable revision of, the content to which AL objects. In such circumstances, full compliance will have to be achieved within 10 days of distributor suspension or AL will terminate the distributorship in question. AL reserves the right to refer deceptive advertising cases to the FTC.

4. Each distributor should report to AL management any instance of a violation of AL's web site/use policy against deceptive advertising by any distributor. Any such complaint will be promptly investigated, using the same system of warning letters, suspension, pay withholding, and termination as is prescribed in 3 above for a comprehensive web search.

5. Each distributor must inform AL if that distributor has a web site and of the URL for that web site. AL will assemble all of the URL information gathered (together with URL owner names, web addresses, and street addresses) on a master list.

6. AL requires that the following statement be projected on a screen visible to all attendees before and after any AL lecture/meeting with distributors and before and after any lecture by Dr. Joel Wallach or any other scientist or medical expert:

That claim is authorized by FDA's letter of April 1, 2003 to this office in settlement of Whitaker et al v. Thompson et al., Civil No. 01-1539. In that letter FDA states that it intends to exercise its enforcement discretion with respect to antioxidant vitamin dietary supplements containing vitamin E and/or vitamin C when the above disclaimer (the second sentence), one of three disclaimers authorized by the April 1, 2003 letter, is placed immediately adjacent to and directly beneath the antioxidants vitamin claim (the first sentence), with no intervening material, in the same size, typeface, and contrast as the claim itself; and (2) the dietary supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Level established by the Institute of Medicine (IOM) of 2000 mg per day for vitamin C and 1000 mg per day for vitamin E. Id. at 2. "Antioxidant vitamin supplements bearing the claim and the disclaimer are required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug and Cosmetic Act, including the applicable requirements for health claims." Id.

"Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive."

That claim is authorized by FDA's "Letter Regarding Dietary Supplement Health Claim for Selenium and Certain Cancers," www.cfsan.fda.gov/~dms/ds-ltr32.html. That letter states that FDA will consider exercising enforcement discretion with respect to selenium supplements that bear the above health claim when (1) the applicable disclaimer is placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself; and (2) the supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding 400 micrograms of selenium per day, which the National Academy of Sciences/Institute of Medicine (NAS/IOM) report concluded is the tolerable upper intake level (UL) from foods and supplements likely to pose no risk of adverse health effects in almost all people. Selenium supplements bearing the claim and disclaimer are required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims.

"Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive."

That claim is authorized by FDA's "Letter Regarding Dietary Supplement Health Claim for Selenium and Certain Cancers," www.cfsan.fda.gov/~dms/ds-ltr32.html (see attached). That letter states that FDA will consider exercising enforcement discretion with respect to selenium supplements that bear the above health claim when (1) the applicable disclaimer is placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself; and (2) the supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding 400 micrograms of selenium per day, which the National Academy of Sciences/Institute of Medicine (NAS/IOM) report concluded is the tolerable upper intake level (UL) from foods and supplements likely to pose no risk of adverse health effects in almost all people. Selenium supplements bearing the claim and disclaimer are required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims.

"Phosphatidylserine (PS) may reduce the risk of cognitive dysfunction in the elderly. Very limited and preliminary scientific research suggests that PS may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence supporting this claim."

is derived from whole soybeans and contains no fat in addition to the fat inherently present in the whole soybeans it contains or from which it is derived. If a dietary supplement containing soy meets the eligibility criteria in 21 C.F.R. § 101.82 FDA has no objection to a dietary supplement using the claim in its labeling. See statement from Dr. Robert J. Moore, Branch Chief, Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration.

"0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects."

That claim is authorized by *Pearson v. Shalala*, 130 F.Supp.2d 105 (D.D.C. 2001) reh'g denied 141 F.Supp.2d 105 (D.D.C. 2001) and FDA's "Letter Regarding a Health Claim for Folic Acid and Neural Tube Defects" www.cfsan.fda.gov/~dms/ds-ltr22.html. The above claim and accompanying disclaimer is identical to the claim and disclaimer stated in the FDA's letter. As the letter states on page 3, FDA intends to exercise its enforcement discretion with respect to folic acid supplements that bear the above health claim (the first sentence) when the above disclaimer (the second and third sentences) is placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. Folic acid supplements bearing the claim and disclaimer must meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims. The dietary supplement bearing the above claim must contain 0.8mg of folic acid per daily dose.

"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."

That claim is authorized by FDA's "Letter Responding to a Request to Reconsider the Qualified Claim for a Dietary Supplement Health Claim for Omega-3 Fatty Acids and Coronary Heart Disease," www.cfsan.fda.gov/~dms/ds-ltr28.html. On page 1 of that letter FDA states that the above claim and disclaimer are acceptable. FDA "would consider exercising its enforcement discretion on an EPA and DHA omega-3 fatty acid dietary supplement bearing those two sentences, i.e., the claim and disclaimer stated immediately above, provided that the supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding 2 grams per day EPA and DHA." *Id.* at 2.

"As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular disease, the evidence in support of the above claim is inconclusive."

That claim is authorized by FDA's settlement of *Whitaker et al. v. Thompson et al.*, Civil Case No. 00-0123 (see FDA press release, www.cfsan.fda.gov/~dms/ds-hclbv.html). FDA intends to exercise enforcement discretion to permit the above health claim (the first sentence) on labels and in labeling of dietary supplements containing folic acid, vitamin B6, and vitamin B12. The disclaimer (the second sentence above) must be immediately adjacent to and directly beneath the claim with no intervening material that separates the claim from the disclaimer. The disclaimer must be in the same size, typeface, and contrast as the claim itself.

"Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer. FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive."

If you are now, or plan to become, an American Longevity (AL) distributor, please be mindful that it is against AL policy for you to use the content of Dr. Wallach's speeches, books, or media presentations to promote or sell any AL product. Please also be aware that it is a violation of federal law for a distributor to make a claim of health benefit for a product that is not backed by competent and reliable scientific evidence. That corroboration of a claim must be on hand (in the form of, for example, well-designed and reliable scientific tests, studies, and analyses on the product in question) before the claim is made. A claim not backed by supporting competent and reliable scientific evidence constitutes deceptive advertising in violation of federal law.

7. The following are examples of prohibited content applicable to all advertising and promotion of AL products (whether on the web, in person, or via media of mass communication):

EXAMPLES OF PROHIBITED AND PERMITTED CLAIMS

Example 1 (prohibited content):

No distributor may use any recording, book, pamphlet, or transcript to promote the sale of an American Longevity product if that recording, book, pamphlet, or transcript associates any nutrient found in an American Longevity product with any effect on a disease or any health benefit unless the precise claim in question has been pre-approved for such use by American Longevity. For example,

A scientist or physician appears at a meeting to educate distributors on the latest science concerning nutrient-disease associations. In the scientist's speech, he explains his opinion that a nutrient found in some of American Longevity's products is useful in the treatment, cure, or prevention of a disease or in improving health, longevity, or wellness. A recording or transcript of that meeting may not be used to promote or sell American Longevity products.

Example 2 (prohibited content):

No distributor may place upon his or her website used to promote or sell American Longevity products any link to another website containing information that associates a nutrient contained in any American Longevity product or any American Longevity product with an effect on a disease or any health benefit unless that specific link has been pre-approved by American Longevity. For example,

You may not include a link tying your website with another that identifies an American Longevity product or an ingredient in that product with a beneficial effect on arthritis, heart disease, cancer, asthma, or any other disease.

Examples 3-7 (prohibited content):

You may not inform a potential purchaser of an American Longevity product that the product or any of its ingredients can treat, cure, or prevent a disease or cause a health benefit unless the specific claim has been pre-approved by American Longevity. For example,

You may not state or imply to a prospective purchaser of an American Longevity product that the product can treat, cure, or prevent arthritis, heart disease, cancer, asthma, or any other disease.

You may not state or imply to a prospective purchaser of an American Longevity product that the product increases longevity.

You may not state or imply to a prospective purchaser of an American Longevity product that the product lessens the incidence of disease.

You may not state or imply to a prospective purchaser of an American Longevity product that the product enhances strength, dexterity, or stamina.

You may not state or imply to a prospective purchaser of an American Longevity product that the product can replace or eliminate the need for any drug therapy for a condition or disease.

Examples 8-12 (prohibited content):

You may not advertise in any medium of mass communication (including via the internet, direct mail, print media, broadcast media, or cable media) that the product or any of its ingredients can treat, cure, or prevent a disease or cause a health benefit unless the specific claim has been pre-approved by American Longevity. For example,

You may not state or imply in any ad for an American Longevity product that the product can treat, cure, or prevent arthritis, heart disease, cancer, asthma, or any other disease.

You may not state or imply in any ad for an American Longevity product that the product increases longevity.

You may not state or imply in any ad for an American Longevity product that the product lessens the incidence of disease.

You may not state or imply in any ad for an American Longevity product that the product enhances strength, dexterity, or stamina.

You may not state or imply in any ad for an American Longevity product that the product can replace or eliminate the need for any drug therapy for a condition or disease.

Examples 13-15 (prohibited content):

You may not represent that an American Longevity product has any effect upon a body structure or function unless the specific claim has been pre-approved by American Longevity. For example,

You may not state or imply that an American Longevity product or product ingredient improves immune system function.

You may not state or imply that an American Longevity product or product ingredient improves joint function.

You may not state or imply that an American Longevity product or product ingredient improves respiration.

By contrast with the above, you may use any claim approved by American Longevity so long as it is used consistent with the approval given and within the same context approved for use. The following are health claims that have been approved or allowed by the Food and Drug Administration and are approved for use by American Longevity distributors provided that FDA's conditions on use of the individual claims are satisfied. The claims must be used in their entirety and within the limits prescribed by FDA.

All supplements, including those bearing any of the below claims, are required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act, including the applicable requirements for health claims. The principal statutory requirements for dietary supplements can be found at 21 U.S.C. § 342(f) (adulteration), 21 U.S.C. § 343(s) (misbranding), 21 U.S.C. §§ 343-2 (labeling exemptions), and 21 U.S.C. § 350b (new dietary ingredients). The principal regulatory requirements can be found at 21 CFR 101. The specific requirements for health claims can be found at 21 U.S.C. § 343(r)(3), 21 CFR 101.14, and 21 CFR 101.70.

Examples (FDA authorized and allowed claims):

"Regular exercise and a healthy diet with enough calcium help teens and young adult white and Asian women maintain good bone health and may reduce their risk of osteoporosis later in life." 21 C.F.R. § 101.72.

That claim is authorized by 21 C.F.R. § 101.72. The claim is an exact replica of the model health claim in section 101.72(e). Dietary supplements qualify as a food upon which the above claim can be made if they satisfy the requirements of section 101.72(c)(ii): (A) the food shall meet or exceed the requirements for a "high" level of calcium as defined in § 101.54(b)(i.e., has 20% or more of the RDA amount for calcium: 1 gram (21 CFR § 101.9(c)(8)(iv))); (B) the calcium content of the product shall be assimilable; (C) dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no USP standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label; and (D) a food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

"Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect." 21 C.F.R. § 101.79.

That claim is authorized by 21 C.F.R. § 101.79. The above health claim is an exact replica of the model health claim in section 101.79(d)(i). Dietary supplements may bear the above claim in accordance with section 101.79(c)(ii): (A) the food shall meet or exceed the requirements for a "good source" of folate as defined in § 101.54(b) (i.e., 40 to 78 micrograms, 10 to 19 percent of 400 micrograms; 21 C.F.R. § 101.79(c)(2)(F)) ; and (B) dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label. The claim cannot be made on foods that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D per serving or per unit (i.e. [list amount]). 21 C.F.R. § 101.79(c)(iii).

"25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of ____ supplies ____ grams of soy protein." 21 C.F.R. 101.82

That claim is authorized by 21 C.F.R. § 101.82. The above health claim is an exact replica of the model health claim in section 101.82(e)(1). Foods may bear the above claim in accordance with section 101.82(c)(ii): (A) the soy protein must come from the legume seed Glycine max; and (B) FDA will assess qualifying levels of soy protein in the following fashion: FDA will measure total protein content by the appropriate method of analysis given in the "Official Methods of Analysis of the AOAC International," as described at § 101.9(c)(7). For products that contain no sources of protein other than soy, FDA will consider the amount of soy protein as equivalent to the total protein content. For products that contain a source or sources of protein in addition to soy, FDA will, using the measurement of total protein content, calculate the soy protein content based on the ratio of soy protein ingredients to total protein ingredients in the product. FDA will base its calculation on information identified and supplied by manufacturers, such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein. According to section 101.82(c)(iii), foods must also meet the following requirements: (A) the food product shall contain at least 6.25 g of soy protein per reference amount customarily consumed of the food product; (B) the food shall meet the nutrient content requirements in § 101.62 for a "low saturated fat" and "low cholesterol" food; and (C) The food shall meet the nutrient content requirement in § 101.62 for a "low fat" food, unless it consists of or