

Footnotes

1. (Footnote No. 4) "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (July 10, 2003). [<http://www.cfsan.fda.gov/~dms/nuttf-e.html>]
2. (Footnote No. 6) See guidance entitled "Interim Evidence-based Ranking System for Scientific Data," July 10, 2003. [<http://www.cfsan.fda.gov/~dms/hclmgi4.html>]
3. (Footnote No. 8) In an intervention study, subjects similar to each other are randomly assigned to either receive the intervention or not to receive the intervention, whereas in an observational study, the subjects (or their medical records) are observed for a certain outcome (i.e., disease). Intervention studies provide the strongest evidence for an effect. See Guidance entitled "Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" (December 22, 1999). [<http://www.cfsan.fda.gov/~dms/ssaguide.html>]
4. (Footnote 14) Consistency of findings among similar and different study designs is important for evaluating causation and the strength of scientific evidence (Hill A.B. The environment and disease: association or causation? Proc R Soc Med 1965;58:295-300) (See reference list for this article); See also Systems to rate the scientific evidence, Agency for Healthcare Research and Quality [<http://www.ahrq.gov/clinic/epcsums/strengthsum.htm#Contents>], defining "consistency" as "the extent to which similar findings are reported using similar and different study designs."
5. (Footnote 16) Food Allergy, American Academy of Allergy Asthma & Immunology, <http://www.aaaai.org/patients/gallery/Default.asp?topic=foodallergy>
6. (Footnote 17) Tips to Remember: Food Allergy, American Academy of Allergy Asthma & Immunology, <http://www.aaaai.org/patients/publicedmat/tips/foodallergy.stm>