

Footnotes



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1. (Footnote No. 1) "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. 3) See guidance entitled "Interim Evidence-based Ranking System for Scientific Data," July 10, 2003. [<http://www.cfsan.fda.gov/~dms/hclmgui4.html>]
3. (Footnote No. 5) 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 are observed or their medical records are reviewed 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 No. 10) Replication of scientific findings is important for evaluating the strength of scientific evidence ([An Introduction to Scientific Research](#), E. Bright Wilson Jr., pages 46-48, Dover Publications, 1990; see also Ioannidis JPA. Contradicted and initially stronger effects in highly cited clinical research. JAMA, 294: 218-228, 2005).
5. (Footnote No. 11) 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 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"))).
6. (Footnote No. 13) PMS is a group of symptoms related to the menstrual cycle including fatigue, trouble sleeping, headaches, irritability, anxiety and/or depression. While PMS is estimated to affect up to 75% of women during their childbearing years, an exact cause of PMS has not been determined. See <http://www.nlm.nih.gov/medlineplus/ency/article/001505.htm>
7. (Footnote No. 14) <http://www.nlm.nih.gov/medlineplus/ency/article/007193.htm>
8. (Footnote No. 15) <http://www.nichd.nih.gov/about/womenhealth/infertility.cfm>