
Footnotes

Footnotes

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/hclmngui4.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 reference list); 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 reference list); 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) National Heart, Lung and Blood Institute (NHLBI), Heart and Blood Vessel Diseases (http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_WhatIs.html) and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and treatment of high blood pressure, 2003. (<http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf>)
7. (Footnote No. 14) National Heart, Lung and Blood Institute (NHLBI), Report of the Working Group on Research on Hypertension During Pregnancy, 2001. (http://www.nhlbi.nih.gov/resources/hyperten_preg/)

8. (Footnote No. 17) National Heart, Lung and Blood Institute (NHLBI), Diseases and Conditions Index
(http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_WhoIsAtRisk.html)
9. (Footnote No. 25) See The Keystone National Policy Dialogue on Food, Nutrition, and Health: Final Report, Keystone Press, 1996, p. 37 (“When clinical trials are feasible, health claims need not arise from a multiplicity of accumulated observational data”)
10. (Footnote No. 27) Subjects who are most likely to have a favorable outcome independent of any intervention are not preferentially selected to receive the intervention being studied (“Guidance for Industry 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>]