

Footnotes

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1. Footnote 2: "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 3: See *Whitaker v. Thompson*, 353 F.3d 947, 950-51 (D.C. Cir 2004) (Reh'g *en banc* denied on March 9, 2004) upholding FDA's interpretation of what constitutes a health claim. [<http://pacer.cadc.uscourts.gov/docs/common/opinions/200401/03-5020a.pdf>]
3. Footnote 4: See guidance entitled "Interim Evidence-based Ranking System for Scientific Data," July 10, 2003. [<http://www.cfsan.fda.gov/~dms/hclmogui4.html>]
4. Footnote 6: 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>]
5. Footnote 12 (see references for Hill, 1965): 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? *Proceedings of the Royal Society of Medicine*. 1965;58:295-300); see also Systems to rate the scientific evidence from the Agency for Healthcare Research and Quality, which defines "consistency" as "the extent to which similar findings are reported using similar and different study designs." [<http://www.ahrq.gov/clinic/epcsums/strengthsum.htm#Contents>]
6. Footnote 15: National Institute Health (NIH), National Institute of Diabetes & Digestive & Kidney Diseases [<http://diabetes.niddk.nih.gov/dm/pubs/overview/index.htm#what>]
7. Footnote 17: NIH, National Diabetes Education Program [<http://ndep.nih.gov/diabetes/WTMD/diabetes.htm>]
8. Footnote 18: NIH, National Diabetes Information Clearinghouse [<http://diabetes.niddk.nih.gov/dm/pubs/insulinresistance/>]
9. Footnote 19: NIH, National Diabetes Information Clearinghouse [<http://diabetes.niddk.nih.gov/complications/index.htm>]
10. Footnote 21: National Toxicology Program, Department of Health and Human Services [<http://ntp-server.niehs.nih.gov/index.cfm?objectid=6DE07683-F1F6-975E-7D52259C338BBE34> and <http://ntp.niehs.nih.gov/index.cfm?objectid=0712660D-C915-D0EC-2CF95E4C710EA647>]
11. Footnote 24: National Heart, Lung and Blood Institute (NHLBI), Heart and Blood Vessel Diseases [[http://www.nhlbi.nih.gov/health/dci/Diseases/Atherosclerosis/Atherosclerosis\\_WhatIs.s.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Atherosclerosis/Atherosclerosis_WhatIs.s.html)] and the National Cholesterol Education Program's (NCEP) third report of the expert panel entitled, "Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)" (2001, page 3) [[http://www.nhlbi.nih.gov/guidelines/cholesterol/atp\\_iii.htm](http://www.nhlbi.nih.gov/guidelines/cholesterol/atp_iii.htm)].