

Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 101.14 and 101.70 have been approved under OMB control no. 0910–0381.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/guidance.html>.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to this Web site after this document publishes in the **Federal Register**.)

1. American Cancer Society, Cancer Facts and Figures, 2004.
2. The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group, "The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers," *New England Journal of Medicine*, 330:1029–1035, 1994.
3. Barton S., "Which Clinical Studies Provide the Best Evidence? The Best RCT Still Trumps the Best Observational Study," *British Medical Journal*, 321:255–256, 2000.
4. Cade, J., R. Thompson, V. Burley, et al., "Development, Validation and Utilization of Food-Frequency Questionnaires—A Review," *Public Health Nutrition*, 5:567–587, 2002.
5. Federal Judicial Center, *Reference Manual on Scientific Evidence*, 2d ed., 2000.
6. Flegal K.M., "Evaluating Epidemiological Evidence of the Effects of Food and Nutrient Exposures," *American Journal of Clinical Nutrition*, 69:1339S–1344S, 1999.
7. Greer N., G. Mosser, G. Logan, et al., "A Practical Approach to Evidence Grading," *Joint Commission Journal on Quality Improvements*, 26:700–712, 2000.
8. Hill A.B., "The Environment and Disease: Association or Causation?," *Proceedings of the Royal Society of Medicine*, 58:295–300, 1965.
9. Hord N.G. and J.I. Fenton, "Context is Everything: Mining the Normal and

Preneoplastic Microenvironment for Insights Into the Diet and Cancer Risk Conundrum," *Molecular Nutrition and Food Research*, 51:100–106, 2007.

10. IOM, Institute of Medicine, "Dietary Supplements: A Framework for Evaluating Safety," National Academies Press, Washington, DC, 2005.
11. Kraemer H.C., K.K. Lowe, D.J. Kupfer, *To Your Health: How to Understand What Research Tell Us About Risk*, Oxford University Press, 2005.
12. Kris-Etherton, P.M. and J. Dietsch, "Design Criteria for Studies Examining Individual Fatty Acid Effects on Cardiovascular Disease Risk Factors: Human and Animal Studies," *American Journal of Clinical Nutrition*, 1590S–1596S, 1997.
13. Lichtenstein, A.H. and R.M. Russell, "Essential Nutrients: Food or Supplements?" *Journal of American Medical Association*, 294:351–358, 2005.
14. Milner J.A., "Diet and Cancer: Facts and Controversies," *Nutrition and Cancer*, 56: 216–224, 2006.
15. National Cancer Institute, Dictionary of Cancer Terms, <http://www.cancer.gov/dictionary>.
16. National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.
17. Omenn, G.S., G.E. Goodman, M.D. Thornquist, et al., "Effects of a Combination of Beta Carotene and Vitamin A on Lung Cancer and Cardiovascular Disease," *New England Journal of Medicine*, 334:1150–1155, 1996.
18. Peto, R., R. Doll, J.D. Buckley, et al., "Can Dietary Beta-Carotene Materially Reduce Human Cancer Rates?," *Nature*, 290:201–208, 1981.
19. Sempos C.T., K. Liu, N.D. Earnst, "Food and Nutrient Exposures: What to Consider When Evaluating Epidemiologic Data," *American Journal of Clinical Nutrition*, 69:1330S–1338S, 1999.
20. Torun B., "Protein-Energy Malnutrition," In: *Modern Nutrition in Health and Disease*, Williams and Williams, New York, 2006.
21. Spilker, B., *Guide to Clinical Studies*, Raven Press, New York, 1991.
22. Subar, A., et al., "Comparative Validation of the Block, Willett, and National Cancer Institute Food Frequency Questionnaires," *American Journal of Epidemiology*, 154:1089–1099, 2001.
23. Szklo M. and F.J. Nieto, *Epidemiology Beyond the Basics*, Aspen Publishing, 2000.
24. Willett, W.C., "Overview of Nutritional Epidemiology," *Nutritional Epidemiology*, Oxford University Press, Oxford, 1990.
25. Willett, W.C., "Issues in Analysis and Presentation of Dietary Data," In *Nutritional Epidemiology*, 2d ed., Oxford University Press, Oxford, 1998.
26. Wilson, E.B., "An Introduction to Scientific Research," General Publishing Co., Toronto, 1990.

Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–0170] (formerly Docket No. 1999D–5424)

Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance entitled "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements," that was issued December 1999.

DATES: The withdrawal is effective January 16, 2009.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 22, 1999 (64 FR 71794), FDA announced the availability of a guidance entitled "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." This guidance is being withdrawn because it is obsolete.

Dated: January 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–N–0103] (formerly Docket No. 2003N–0069)

Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.