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.
- 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. Dietschy, "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.

[FR Doc. E9–957 Filed 1–15–09; 8:45 am] **BILLING CODE 4160–01–S** 

# 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:

Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740, 301–436–2579.

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.

[FR Doc. E9–964 Filed 1–15–09; 8:45 am] BILLING CODE 4160–01–S

## 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.

4.300

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the guidance entitled "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data" that was issued on July 10, 2003.

**DATES:** The withdrawal is effective January 16, 2009.

#### FOR FURTHER INFORMATION CONTACT:

Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740, 301–436–2579.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 11, 2003 (68 FR 41387), FDA announced the availability of a guidance entitled "Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data." This guidance is being withdrawn because it is obsolete.

Dated: January 13, 2009.

#### Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-959 Filed 1-15-09; 8:45 am] BILLING CODE 4160-01-S

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions

of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

### Proposed Project: Uncompensated Services Assurance Report (OMB No. 0915–0077)—Extension

Under the Hill-Burton Act, the Government provides grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance, facilities are required to provide services to persons unable to pay. A condition of receiving this assistance requires facilities to provide assurances periodically that the required level of uncompensated care is being provided, and that certain notification and recordkeeping procedures are being followed. These requirements are referred to as the uncompensated services assurance.

### ESTIMATE OF INFORMATION COLLECTION BURDEN

		001110			
Type of requirement and regulatory citation	No. of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
	Disclosure burden	(42 CFR)			
Published Notices (124.504(c))	86		1 86	0.75	65
Individual Notices (124.504(c))	86		1 86	43.6	3,750
Determinations of Eligibility (124.507)	86	8	7,396	0.75	5,547
Subtotal Disclosure Burden					9,362
	Reporting	)		1	1
Uncompensated Services Report—HRSA-710 Form					
(124.509(a))	10		1 10	11.0	110
Application for Compliance Alternatives:					
Public Facilities (124.513)	4		1	6.0	24
Small Obligation Facilities (124.514(c))	0				
Charitable Facilities (124.516(c))	2		1 2	6.0	12
Annual Certification for Compliance Alternatives:					
Public Facilities (124.509(b))	37		1 37	0.5	18.5
Charitable Facilities (124.509(b))	4		1 14	0.5	7
Small Obligation Facilities (124.509(c))	0		1 (	0.5	
Complaint Information (124.511(a)):					
Individuals	10		1 10	0.25	3
Facilities	10		1 10		5
Subtotal Reporting Burden					179.5
Recordkeeping			Number of recordkeepers	Hours per year	Total hour burden
Non-alternative Facilities (124.510(a))			86	50	4,300
, , , , , , ,					<u> </u>

Subtotal Recordkeeping Burden .....