

contains similar provisions for drugs and medical devices (21 U.S.C. 352(a)) and cosmetics (21 U.S.C. 362(a)). In some cases, the courts have interpreted the act to protect "the ignorant, the unthinking, and the credulous" consumer. See, e.g., *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951); *United States v. An Article of Food* \* \* \* "*Manischewitz* \* \* \* *Diet Thins*," 377 F. Supp. 746, 749 (E.D.N.Y. 1974). In other cases, the courts have interpreted the act to require evaluation of claims from the perspective of the ordinary person or reasonable consumer. See, e.g., *United States v. 88 Cases, Bireley's Orange Beverage*, 187 F.2d 967, 971 (3d Cir.), cert. denied 342 U.S. 861 (1951). FDA believes that the latter standard is the appropriate standard to use in determining whether a claim in the labeling of a dietary supplement or conventional food is misleading.

The reasonable consumer standard more accurately reflects FDA's belief that consumers are active partners in their own health care who behave in health promoting ways when they are given accurate health information. In addition, the reasonable consumer standard is consistent with the governing first amendment case law precluding the Government from regulating the content of promotional communication so that it contains only information that will be appropriate for a vulnerable or unusually credulous audience. Cf. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 73-74 (1983) ("the government may not 'reduce the adult population \* \* \* to reading only what is fit for children.'") (quoting *Butler v. Michigan*, 352 U.S. 380, 383 (1957)).

Based on the FTC's success in policing the marketplace for misleading claims in food advertising, FDA believes that its own enforcement of the legal and regulatory requirements applicable to food labeling will not be adversely affected by use of the "reasonable consumer" standard in evaluating labeling for dietary supplements and conventional foods. Explicit FDA adoption of the reasonable consumer standard will rationalize the regulatory environment for food promotion while both protecting and enhancing the public health.

This guidance represents the agency's current thinking on qualified health claims in the labeling of conventional foods and dietary supplements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach

satisfies the requirements of the applicable statute and regulations.

This guidance is a Level 1 guidance under FDA's good guidance practices (GGP) regulation (21 CFR 10.115). Under § 10.115(g)(2), the guidance is being implemented immediately, without prior public comment, to help ensure that FDA's policies on health claims in food labeling comply with the governing first amendment case law. Consistent with the GGP regulation, FDA is now soliciting comment on the guidance and will revise it, if warranted.

FDA tentatively concludes that this guidance contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

## II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see ADDRESSES). Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/dms/guidance.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: December 17, 2002.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space

available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Cancer Institute Director's Consumer Liaison Group.

*Date:* January 6-7, 2003.

*Time:* 8 a.m. to 1 p.m.

*Agenda:* To discuss the future of the DCLG and to meet with NCI staff to discuss their research plans.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Elaine Lee, Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594-3194.

Information is also available on the Institute's/Center's home page: [deainfo.nci.nih.gov/advisory/dclg/dclg.htm](http://deainfo.nci.nih.gov/advisory/dclg/dclg.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 12, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.