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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0515]

Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements." This guidance updates the agency's approach to implementing the court of appeals decision in *Pearson* v. *Shalala* (*Pearson*) to include conventional foods. FDA is taking this action to inform interested persons of the circumstances under which the agency intends to consider exercising its enforcement discretion to permit qualified health claims for conventional foods and dietary supplements.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Kathleen Ellwood, Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

After the enactment of the Nutrition Labeling and Education Act of 1990 (the NLEA), FDA issued regulations establishing general requirements for health claims in food labeling (58 FR 2478, January 6, 1993 (conventional foods); 59 FR 395, January 4, 1994 (dietary supplements)). By regulation, FDA adopted the same procedure and standard for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods (see 21 U.S.C. 343(r)(3),(r)(4)). The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (21 CFR 101.14(d),(e); 21 CFR 101.70)). The standard requires a finding of "significant scientific agreement" before FDA may authorize a health claim by regulation § 101.14(c) (21 CFR 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that

the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (21 CFR 101.14(c)). Without a regulation authorizing use of a particular health claim, a food bearing the claim is subject to regulatory action as a misbranded food (see 21 U.S.C. 343(r)(1)(B)), a misbranded drug (see 21 U.S.C. 352(f)(1)), and an unapproved new drug (see 21 U.S.C. 355(a)).

In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. The district court ruled for FDA (14 F. Supp. 2d 10 (D.D.C. 1998)). However, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)). The appeals court held that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. On March 1, 1999, the Government filed a petition for rehearing *en banc* (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).

In the **Federal Register** of October 6, 2000 (65 FR 59855), FDA published a notice announcing its intention to exercise enforcement discretion with regard to certain categories of dietary supplement health claims that do not meet the significant scientific agreement standard in § 101.14(c). The notice set forth criteria for when the agency would consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling. FDA is

now issuing these criteria in the form of guidance and is expanding them to include health claims in the labeling of conventional foods. The October 6, 2000, **Federal Register** notice also described the process that FDA intends to use to respond to future health claim petitions; FDA is reissuing this information in the form of guidance. FDA is also clarifying that the agency will use a "reasonable consumer" standard in evaluating whether food labeling is misleading.

FDA believes that this guidance will assist food manufacturers and distributors in formulating truthful and nonmisleading messages about the health benefits of their products. As the agency has found (52 FR 28843, August 4, 1987), food labeling is a vehicle for "improv[ing] the public's understanding about the health benefits that can result from adhering to a sound and nutritious diet." Food labeling can also communicate information concerning positive health consequences, beyond basic nutrition, of consuming particular foods. Such consequences can be communicated in nutrient content claims or health claims, for example.

Consumers are more likely to respond to health messages in food labeling if the messages are specific with respect to the health benefits associated with particular substances in the food. According to the Bureau of Economics Staff of the Federal Trade Commission (FTC) (Bureau of Economics Staff, "Advertising Nutrition & Health: Evidence from Food Advertising 1977–1997" (September 2002)), "consumers are not as responsive to simple nutrient claims" as they are to health claims. This difference in responsiveness reflects the explicit linkage in health claims of health benefits to particular nutrients or food components. If consumers understand the health advantages of consuming foods containing particular components, they are more likely to

select foods containing those substances. In the aggregate, decisions by individual consumers to incorporate beneficial foods into their diets improve public health.

Conventional food manufacturers and distributors are more likely to include specific health claims in labeling if FDA makes clear their entitlement under the law to engage in such communications with consumers. There is evidence, reviewed by the FTC Bureau of Economics Staff (Bureau of Economics Staff, "Advertising Nutrition & Health: Evidence from Food Advertising 1977–1997" (September 2002)), that the content of food promotional messages responds to changes in applicable legal and regulatory requirements. As the FTC report stated, "the evidence is consistent with the hypothesis that a more open environment leads to competitive pressures that induce producers to reveal information on more nutrient dimensions in advertising." By making clear the lawfulness of conventional foods labeled with truthful and nonmisleading health claims, FDA believes that this guidance will precipitate greater communication in food labeling of the health benefits of consuming particular foods, thereby enhancing the public's health.

As discussed further in the guidance, to meet the criteria for a qualified health claim, the petitioner would need to provide a credible body of scientific data supporting the claim. Although this body of data need not rise to the level of significant scientific agreement defined in FDA's previous guidance, the petitioner would need to demonstrate, based on a fair review by scientific experts of the totality of publicly available scientific information, that the "weight of the scientific evidence" supports the proposed claim. The test is not whether the claim is supported numerically (i.e., whether more studies support the proposed claim than not), but rather whether the pertinent data

and information presented in those studies is sufficiently scientifically persuasive. For a claim that meets the "weight of the scientific evidence" standard, the agency would decline to initiate regulatory action, provided the claim is qualified by appropriate language so consumers are not misled as to the degree of scientific uncertainty that would still exist.

FDA anticipates that this policy will facilitate the provision to consumers of additional, scientifically supported health information. FDA expects that, as scientific inquiry into the role of dietary factors in health proceeds, particular qualified health claims will be further substantiated, while for other qualified health claims the "weight of the scientific evidence" will shift from "more for" to "more against." It is conceivable, therefore, that the information provided to consumers through qualified health claims in food labeling could change over time. FDA nevertheless believes that the dissemination of current scientific information concerning the health benefits of conventional foods and dietary supplements should be encouraged, to enable consumers to make informed dietary choices yielding potentially significant health benefits.

As FDA facilitates the provision of scientifically supported health information for food products, the agency must also strengthen its enforcement of the rules prohibiting unsubstantiated or otherwise misleading claims in food labeling. In assessing whether food labeling is misleading, FDA will use a "reasonable consumer" standard, as discussed below in section I of this document. Use of this standard will contribute to the rationalization of the legal and regulatory environment for food promotion, by making FDA's regulation of dietary supplement and conventional food labeling consistent with the FTC's regulation of advertising for these products.

The FTC's jurisdiction over food advertising derives from sections 5 and 12 of the FTC Act (15 USC 45 and 52), which broadly prohibit unfair or deceptive commercial acts or practices and specifically prohibit the dissemination of false advertisements for foods, drugs, medical devices, or cosmetics. The FTC has issued two policy statements, the Deception Policy Statement (appended to Cliffdale Assocs., Inc., 103 F.T.C. 110, 174 (1984)) and the Statement on Advertising Substantiation (appended to Thompson Med. Co., 104 F.T.C. 648, 839 (1984)), that articulate the basic elements of the deception analysis employed by the FTC in advertising cases. According to these policies, in identifying deception in an advertisement, the FTC considers the representation from the perspective of a consumer acting reasonably under the circumstances: "The test is whether the consumer's interpretation or reaction is reasonable." 103 F.T.C. at 177.

FDA's general statutory authority to regulate food labeling derives from section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(a)(1)), which deems a food misbranded if its labeling is false or misleading "in any particular."[1] The act 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

[1] The act does not require FDA to have survey evidence or other data before the agency is entitled to proceed under section 403(a)(1) of the act. FDA nevertheless recognizes that survey data and other evidence will be helpful in evaluating whether consumers are misled by a particular claim. For example, surveys, copy tests, and other reliable evidence of consumer interpretation can be helpful in assessing the particular message conveyed by a statement that FDA believes constitutes an implied claim.

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
December 17, 2002.

William K. Hubbard
William K. Hubbard,
Associate Commissioner for Policy and Planning.

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