

Guidance for Industry

Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements

Submit written comments regarding this guidance document to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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I. INTRODUCTION

As part of its continuing effort to implement the court of appeals decision in *Pearson v. Shalala* (*Pearson*), the Food and Drug Administration (FDA) is issuing guidance on qualified health claims in the labeling of conventional foods and dietary supplements. This document updates the agency's approach to implementing *Pearson* to include conventional foods and provides guidance to industry on the circumstances under which FDA will consider exercising its enforcement discretion to permit health claims that do not meet the "significant scientific agreement" standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims. This document also describes the process and standards that FDA intends to use to respond to future health claim petitions. Finally,

FDA is clarifying that the agency will use the "reasonable consumer" standard in evaluating food labeling claims.

II. 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 (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 21 CFR 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 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 believes that this guidance will assist food manufacturers and distributors in formulating truthful and non-misleading 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 non-misleading 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.

III. POLICY

FDA intends to continue considering the exercise of enforcement discretion for dietary supplement health claims in appropriate circumstances, and it intends to expand the exercise of enforcement discretion to conventional food health claims under the same circumstances. Specifically, the agency will consider exercising enforcement discretion for a health claim that is not the subject of an authorizing regulation under the following circumstances: (1) The claim is the subject of a health claim petition that meets the requirements of 21 CFR 101.70 and has been filed for comprehensive review under 21 CFR 101.70(j)(2); (2) the scientific evidence in support of the claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the scientific evidence; (3) consumer health and safety are not threatened; and (4) the claim

meets the general requirements for health claims in 21 CFR 101.14, except for the requirement that the evidence supporting the claim meet the significant scientific agreement standard and the requirement that the claim be made in accordance with an authorizing regulation. The first and fourth criteria are requirements found in the FDA regulations cited above; the second and third come directly from the court of appeals opinion in *Pearson*.

To the extent possible, FDA will consider these criteria while it is evaluating the petition and will state its conclusions in a letter to the petitioner; however, some criteria will have to be evaluated after the fact, because they involve information or circumstances that cannot be determined from the petition. For example, FDA will not be able to determine whether the entire claim (including the disclaimer) appears in one place without intervening material, as required by 21 CFR 101.14(d)(2)(iv), until it actually sees the claim on products in the marketplace. There may be additional factors that FDA would consider in deciding whether to exercise enforcement discretion with respect to a particular claim; the agency intends to outline such additional factors in its letter to the petitioner. Finally, some provisions of 21 CFR 101.14 may not be relevant to a particular claim. The agency also intends to identify any such provisions in its letter to the petitioner.

Consistent with the requirement in the NLEA and regulations that health claims be reviewed by FDA before they appear in food labeling, FDA intends to consider exercising enforcement discretion only if a petition to authorize the health claim has been submitted; the agency has filed the petition; the agency has completed its scientific evaluation of the claim and communicated that evaluation by letter to the petitioner; and the criteria previously described are met. See 21 U.S.C. 343(r)(3),(r)(4); 21 CFR 101.14, 101.70.

Consistent with the October 2000 Federal Register notice, FDA intends to respond to health claim petitions that have been filed for comprehensive review in one of the following three ways:

- (1) If FDA determines that the significant scientific agreement standard is met, the agency will propose to authorize the health claim. FDA will consider using its interim final rule authority under 21 U.S.C. 343(r)(7)(A)(iii) to allow use of the health claim immediately upon publication of the proposal.
- (2) If FDA determines that the significant scientific agreement standard is not met, but that the scientific evidence in support of the claim outweighs the scientific evidence against the claim (taking into account both quality and quantity) and the other threshold criteria listed above are met, FDA will consider exercising enforcement discretion with regard to conventional foods and/or dietary supplements that bear the health claim with appropriate qualifying language. The petitioner will be notified in writing of this intention. The letter to the petitioner will outline the agency's rationale for its determination that the evidence does not meet the significant scientific agreement standard set forth in 21 CFR 101.14(c) and then state the circumstances under which the agency would ordinarily expect to exercise enforcement discretion for use of the claim.

(3) If FDA determines that the significant scientific agreement standard is not met and that the evidence supporting the claim is outweighed by evidence against the claim (taking into account both quality and quantity), or the substance poses a threat to health, or that any of the other threshold criteria previously listed are not met, FDA intends to deny the petition. The denial letter to the petitioner will: (1) Outline the agency's rationale for its determination that the evidence does not meet the significant scientific agreement standard set forth in 21 CFR 101.14(c); and (2) explain why FDA believes that the scientific evidence for the claim is outweighed by the evidence against the claim, that the claim would be otherwise misleading even if qualified, or that authorizing a health claim would pose a threat to consumer health or safety.

As noted in the October 2000 Federal Register notice, this process is consistent with case law holding that FDA has wide latitude in matters of enforcement discretion. (See, e.g., *Heckler v. Chaney*, 470 U.S. 821 (1985); *Schering v. Heckler*, 779 F.2d 683 (D.C. Cir. 1985).) It is also consistent with the *Pearson* decision, which described several circumstances in which FDA might be justified in banning certain health claims outright--e.g., where consumer health and safety are threatened, or where FDA can demonstrate that a health claim would be misleading even if qualified (see *Pearson*, 164 F.3d at 650, 657-60). For example, the court said that FDA could prohibit a health claim where the evidence in support of the claim is outweighed by evidence against the claim, taking into account both quality and quantity (*Pearson*, 164 F.3d at 659 & n.10).

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 information available, 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 increase 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. 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 Commission 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 (FDCA or Act) (21 USC 343(a)(1)), which deems a food misbranded if its labeling is false or misleading "in any particular."¹ The FDCA contains similar provisions for drugs and medical devices (21 USC 352(a)) and cosmetics (21 USC 362(a)). In some cases, the courts have interpreted the FDCA 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 is consistent with the FTC deception analysis, which means its use by FDA will contribute to the rationalization of the legal and regulatory environment for food promotion. The standard is also 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)). Finally, the

¹ The FDCA does not require FDA to have survey evidence or other data before the agency is entitled to proceed under section 403(a)(1). 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.

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.

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.