



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20580

**BEFORE THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**In the Matter of  
Regulations on Statements Made for Dietary Supplements  
Concerning the Effect of the Product on the Structure or  
Function of the Body; Proposed Rule**

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[Docket No. 98N-0044]

**Comments of the Staff of the  
Bureau of Consumer Protection  
of the Federal Trade Commission\***

**August 27, 1998**

**I. INTRODUCTION**

The Food and Drug Administration (FDA) is soliciting comment on a proposed rule that defines when a label statement about a dietary supplement would be considered a claim about the product's effect on a normal structure or function of the body (structure/function claim), and thus be permitted in labeling. The proposed rule also establishes criteria for determining when a label statement would be considered a claim about a supplement's ability to diagnose, cure, mitigate, treat, or prevent disease (disease claim), and thus be prohibited in labeling. Because the Federal Trade Commission (FTC) has jurisdiction over claims made in supplement advertising, the staff of the FTC's Bureau of Consumer Protection is submitting this comment on an issue that is central to both agencies' treatment of dietary supplements: *the requirement that claims for dietary supplements be substantiated.*

**II. BACKGROUND**

The FTC and FDA have complementary jurisdiction to address the marketing of dietary supplements. Under the terms of a liaison agreement governing the division of responsibilities between the two agencies, the FTC has primary responsibility for advertising and FDA has primary responsibility for labeling.<sup>(1)</sup> Their shared jurisdiction means that the two agencies coordinate closely to ensure that their actions are consistent to the fullest extent feasible given the statutory authority of each.

The regulation of supplement labeling claims by FDA is governed by the Dietary Supplement Health and Education Act of 1994 (DSHEA).<sup>(2)</sup> Under Section 6 of DSHEA, codified as Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDCA), structure/function claims are permitted in dietary supplement labeling without prior authorization by FDA, provided the manufacturer has substantiation for the claims and complies with certain notification and disclaimer requirements.<sup>(3)</sup>

Claims made in supplement advertising are addressed primarily under the Federal Trade Commission Act (FTC Act). Section 5 of the FTC Act broadly prohibits deceptive and unfair acts or practices in or affecting commerce,<sup>(4)</sup> including deceptive advertising. In addition, supplement advertising falls under Sections 12 and 15 of the FTC Act.

These two sections prohibit false advertisements of foods, drugs, devices, services and cosmetics, which are defined as advertisements that are misleading in a material respect.(5) The FTC has developed a legal framework for assessing advertising claims pursuant to these provisions. This framework, set out in the FTC's Deception Policy Statement and its Substantiation Policy Statement,(6) can be distilled into two fundamental legal principles: 1) advertising must be truthful and not misleading; and 2) advertisers must have substantiation for all objective claims before the claims are disseminated.(7)

### III. SUBSTANTIATION OF STRUCTURE/FUNCTION CLAIMS

Under Section 403(r)(6) of the FDCA, as amended by DSHEA, structure/function claims in supplement labeling must be substantiated.(8) The substantiation requirement is set out in the existing rule implementing the notification procedures for such claims.(9) The newly proposed amendment to this rule defining permitted structure/function claims does not, however, explicitly restate that such claims be substantiated.(10)

*FTC staff recommends that any final rule reiterate explicitly the requirement that structure/function claims be adequately substantiated.*(11) Although the focus of FDA's proposed revision is on the distinction between permissible structure/function claims and impermissible disease claims, the need for substantiation should also be emphasized. Otherwise, this basic statutory requirement may be missed amid the details of how to classify claims. Adequate substantiation is critical to ensuring that consumers receive truthful and accurate information about the benefits of dietary supplements. Unless the information being presented is supported by sound evidence, consumers cannot make informed decisions about whether and how to use these products.

*Staff also recommends that FDA include guidance in the final rule as to what constitutes adequate substantiation of a structure/function claim.* This would help address uncertainty within the dietary supplement industry about how FDA applies the DSHEA substantiation requirement. It would also clarify how FDA's approach to substantiation relates to FTC's substantiation standard.

The November 1997 Report of the Commission on Dietary Supplement Labels (Supplement Commission Report) provides important guidance on the issue of substantiation of supplement labeling claims.(12) It states that claims should be supported by "scientifically valid evidence;"(13) suggests some general principles that should govern the amount and type of evidence necessary to meet the DSHEA substantiation requirement;(14) and notes that the evidence needed will vary depending on the nature of the statement being made. The Supplement Commission Report acknowledges that claims can be supported by various types of evidence, including human studies, animal studies, in vitro studies, epidemiologic data, and historical use. It also singles out well-designed and controlled clinical studies, particularly those published in peer-reviewed scientific journals, as important and credible evidence. Finally, the Supplement Commission Report stresses the importance of considering all relevant evidence, including contrary findings, and suggests that the "weight of evidence" should substantiate the claim.(15)

The FTC's approach to substantiation of advertising claims corresponds in many ways to the principles for substantiating labeling claims outlined in the Supplement Commission Report.(16) Both approaches apply a flexible standard governed in large part by the way the claim is presented. Under FTC law, identifying the claim conveyed by an ad is the first step in any determination of what level of support is required to substantiate that claim.(17) The FTC will look at the overall impression of the ad and consider statements in the context of all elements of the ad.(18) For claims about the efficacy and safety of dietary supplement products, the FTC typically holds advertisers to a substantiation standard referred to in numerous FTC orders as "competent and reliable scientific evidence" and defined as:

Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.(19)

The FTC's application of this standard shares many similarities with the Supplement Commission Report's proposal for "scientifically valid evidence." Consistent with the Supplement Commission's guidance, the FTC considers all forms of research when evaluating substantiation. As a general matter, the FTC considers well-controlled human clinical studies to be the most reliable form of evidence, but also takes into account other forms of research, including epidemiologic evidence, animal and in vitro studies in appropriate circumstances.<sup>(20)</sup> Like the Supplement Commission approach, the FTC looks at studies in the context of the entire body of scientific literature, considers all relevant evidence, including contrary evidence, and has indicated that the weight of evidence should support the claim.<sup>(21)</sup>

FDA has indicated, in its comments on the Supplement Commission Report, that the agency concurs with the Supplement Commission's guidance on substantiation of structure/function claims.<sup>(22)</sup> FDA's agreement with that guidance is important, because it clarifies how the agency interprets and applies the DSHEA substantiation standard. FTC staff believes that it would be helpful for FDA to reference that guidance directly in the proposed rule. By highlighting the requirement that structure/function claims in labeling must be substantiated, and by giving guidance on how the agency will apply that substantiation requirement, FDA will help ensure that industry members will understand what is required to have adequate support for their claims.

Respectfully Submitted,

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#### Endnotes:

\* These comments are the views of the staff of the Bureau of Consumer Protection. They do not necessarily represent the views of the Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Michelle Rusk (202-326-3148) or Anne Maher (202-326-2987).

1. FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH) ¶ 9851 (1971). Although the Liaison Agreement does not refer explicitly to dietary supplements, the two agencies follow the same division of roles for dietary supplements as currently used for food products. Under FDA law, dietary supplements are deemed to be foods. 21 U.S.C. § 201(ff).
2. Pub. L. No. 103-417, 108 Stat. 4325 (1994).
3. 21 U.S.C. § 343(r)(6).
4. 15 U.S.C. § 45.
5. 15 U.S.C. §§ 52, 55. Section 12 of the FTC Act, 21 U.S.C. § 52.
6. Deception Policy Statement, Letter Dated Oct. 14, 1983 from Commission to Chairman John D. Dingell, appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174 (1984); Substantiation Policy Statement, appended to Thompson Medical Co., 104 F.T.C. 648, 839 (1984).

7. While the majority of advertising cases are brought pursuant to the FTC's deception authority, the agency can also challenge advertising under its unfairness jurisdiction. An unfair practice is one that causes, or is likely to cause, substantial injury to consumers, which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition. 15 U.S.C. § 45 (n).

8. 21 U.S.C. § 343(r)(6)(B).

9. The current rule implementing the notification procedures for structure/function claims, includes the provision that the notifying firm must certify that it has "substantiation that the statement is truthful and not misleading." 21 C.F.R. § 101.93 (a)(3).

10. 21 C.F.R. § 101.93 (f) (proposed). The new provision on structure/function claims merely states that dietary supplement labels may bear such claims "subject to the requirements of this section."

11. Staff suggests including an explicit reference to the substantiation requirement in proposed Section 101.93(f).

12. Report of the Commission on Dietary Supplement Labels (Nov. 1997). The Report frequently refers to supplement labeling claims as "statements of nutritional support." Structure/ function claims are one category of such statements.

13. *Id.* at 38.

14. *Id.* at 42-43.

15. *Id.* at 43.

16. The FTC's approach to substantiation of advertising claims is detailed in its Substantiation Policy Statement contained in *Thompson Medical Co.*, 104 F.T.C. at 839 (1984).

17. The various factors that the FTC will consider in determining the level of substantiation required are: 1) the type of product advertised; 2) the type of claim; 3) the benefits of a truthful claim; 4) the ease of developing substantiation for the claim; 5) the consequences of a false claim; and 6) the amount of substantiation experts in the field believe is necessary. See *Pfizer Inc.*, 81 F.T.C. 23, 64 (1972). See also Substantiation Policy Statement, *Thompson Medical Co.*, 104 F.T.C. at 840.

18. See, e.g., *Thompson Medical Co.*, 104 F.T.C. 648, 790 (1984). FDA's proposed rule similarly recognizes the importance of looking at all elements of a label in context to determine what claims are conveyed either expressly or implicitly by the ad. 101 C.F.R. § 101.93(g)(2) (proposed rule). FDA acknowledges, in its discussion of the proposed rule, that a statement that by itself would be considered an acceptable structure/function claim could become a disease claim if, "in context, an effect on disease were express or implied." 63 Fed. Reg. at 23626. Staff believes that the context of a claim is critical to identifying what message is actually conveyed to consumers, not only in labeling but also in advertising.

19. See, e.g., *Venegas, Inc.*, C-3781 (Jan. 23, 1998)(consent); *Global World Media Corp.*, C-3772 (Oct. 9, 1997)(consent); *Nutrition 21*, C-3758 (July 11, 1997)(consent); *Schering Corp.*, 118 F.T.C. 1030 (1994)(consent).

20. There may be instances, for example, where animal research is widely considered to be an acceptable substitute for human research in a particular field of study, or where human research is prohibitively expensive or infeasible for other reasons.

21. In its Food Policy Statement, for example, the FTC provided that, when a claim is based on science that is inconsistent with the larger body of evidence, it is likely to be misleading, even if qualified. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28388, 28393-94 (June 1, 1994).

22. FDA's notice states, "The Commission Report includes guidance on what quantity and quality of evidence should be used to substantiate claims made under section 403(r)(6) of the act.... The agency agrees with the guidance." Dietary Supplements; Comments on Report of the Commission on Dietary Supplement Labels, 63 Fed. Reg. 23633, 23635 (April 29, 1998).