

The Federal Trade Commission's Regulation of Advertising Claims for Dietary Supplements

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I. INTRODUCTION

This article discusses the role of the Federal Trade Commission (FTC) in the regulation of advertising, illustrates the application of the Commission's regulatory approach to dietary supplements, and offers the authors' thoughts on the likely implications of the Dietary Supplement Health and Education Act (DSHEA)¹ for the FTC.

II. FTC REGULATION OF ADVERTISING

The FTC is primarily a law enforcement agency. The FTC's regulation of advertising is based on section 5(a)(1) of the Federal Trade Commission Act,² which declares "unfair or deceptive acts or practices in or affecting commerce" to be unlawful,³ and section 5(a)(2) of the Act, which empowers and directs the Commission to prevent the use of such acts or practices.⁴ In addition, section 12 prohibits false advertisements that are likely to induce the purchase of food, drugs, devices, or cosmetics,⁵ while section 15 defines false advertisements (for the purposes of section 12) as those that are misleading in a material respect.⁶

The FTC and the Food and Drug Administration (FDA) have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics, and devices. The agencies operate under a long-standing liaison agreement under which the FDA has primary responsibility for regulating the labeling of these products, while the FTC has primary responsibility for ensuring that the products' advertising is truthful and not misleading.⁷

A. Principles of Enforcement

Two major principles form the basis of the FTC's regulation of advertising pursu-

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¹ Pub. L. No. 103-417, 108 Stat. 4325 (1994) (to be codified at 21 U.S.C. §§ 321(ff), (s)(6), note, 331(u), 342(f), (g), 343(q)(5)(F), (r)(6), (s), note, 342-2, 350(b)(2), (c)(1)(B), 350b, 42 U.S.C. § 287c-11).

² Act of Sept. 26, 1914, ch. 311, 38 Stat. 717 (1914), as amended 15 U.S.C. §§ 41-64 (1988).

³ 15 U.S.C. § 45(a)(1).

⁴ *Id.* § 45(a)(2)(b).

⁵ *Id.* § 52(a)(2).

⁶ *Id.* § 55(a)(1).

⁷ Working Agreement Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971) (updating and replacing prior agreements of June 1954 and Jan. 1958).

ant to its statutory mandate: advertising must be truthful and not misleading, and advertisers must have substantiation for all objective advertising claims before the claims are disseminated.⁸

With respect to the first principle, it is important to note that advertisers are responsible for claims that are reasonably implied from their advertisements, as well as claims that are expressly stated therein. Advertisements can mislead consumers by what they do *not* say as well as by what they *do* say. Thus, it may be deceptive under the Federal Trade Commission Act to omit information from an advertisement if that information is necessary to prevent the advertisement from conveying a misleading claim. It is not necessary that an advertiser intend to mislead consumers for that advertiser to be held liable for a misleading claim.

With respect to the second principle, the type and amount of substantiation required depends on the specifics of each case.⁹ As a general matter, for the types of health-related claims commonly made in advertising for dietary supplements, the Commission normally requires an advertiser to have competent and reliable scientific evidence. This substantiation standard of "competent and reliable scientific evidence" has been defined in numerous FTC cases to mean "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."¹⁰

B. *The FTC's Evaluation of Substantiation*

There are a few important aspects of the FTC's substantiation policy that need to be emphasized. First, the Commission is serious about the requirement that studies relied on to support claims must be competent and reliable. Studies that are not designed and conducted in a scientifically valid and rigorous manner are unacceptable. For instance, in a case challenging claims of increased stamina, endurance, and overall physical fitness for a wheat germ oil product, the Commission rejected "university research" proffered by the advertiser as substantiation for the claims on the grounds that it did not reach the level of "competent and reliable scientific evidence."¹¹

Second, the FTC evaluates specific studies offered as substantiation for advertising claims in light of — not in lieu of — the relevant body of surrounding scientific

⁸ These requirements are set forth in two policy statements issued in the early 1980s. See FTC Policy Statement on Advertising Substantiation, 48 Fed. Reg. 10,471 (1984), reprinted in Thompson Med. Co., 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987) [hereinafter Substantiation Statement]; Cliffdale Assoc., Inc., 103 F.T.C. 110, 176 (1984), reprinted as appendix in letter from the FTC to the Hon. John D. Dingell, Chairman, Comm. on Energy and Commerce, U.S. House of Reps. (Oct. 14, 1983) [hereinafter Deception Statement].

⁹ Determining the appropriate level of substantiation involves consideration of a number of factors. These factors 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 that experts in the field believe is necessary. See Pfizer Inc., 81 F.T.C. 23, 64 (1972); Thompson, 104 F.T.C. at 813, 821; Bristol-Myers v. FTC, 102 F.T.C. 21, 321 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985). See also Substantiation Statement, in Thompson, 104 F.T.C. at 840.

¹⁰ E.g., Schering Corp., Dkt. No. 9232 (Nov. 4, 1994) (consent); L & S Research Corp., C-3534 (Oct. 6, 1994) (consent); Miles, Inc., 114 F.T.C. 31 (1991) (consent); Nature's Way Prods., 113 F.T.C. 293 (1990) (consent).

¹¹ Viobin Corp., 108 F.T.C. 385 (1986) (consent).

evidence. Thus, studies are not assessed in isolation, but in the context of other available data. This point is illustrated by a recent FTC action that challenged weight loss claims for a fiber tablet in which the advertiser relied on six studies as substantiation.¹² The administrative law judge found that each of the studies had flaws that raised questions about its reliability and that, in light of a large body of surrounding evidence that the amount and type of fiber involved was unlikely to cause weight loss, these flaws were significant.¹³

Finally, proffered substantiation must support the claims conveyed by advertising. This may sound like common-sense, but failure to satisfy this requirement is perhaps the most frequently noted deficiency in advertisers' attempts to substantiate claims. In the fiber tablet case, for instance, one of the major flaws with the studies proffered was that they all involved use of the product in conjunction with a conscious reduction of caloric intake. The administrative law judge found, however, that the advertisements implied that the product promoted weight loss without the need to consciously follow a diet.¹⁴ The studies referred to therefore did not support the efficacy of the product as advertised.

III. FTC ACTIONS AGAINST CLAIMS FOR DIETARY SUPPLEMENTS

The FTC has been quite active in the area of dietary supplement advertising claims. Since 1990, the Commission has taken formal action against more than twenty-five companies that promoted supplements for a wide variety of health-related purposes.¹⁵ Many of these cases have challenged claims for multiple products. FTC actions have involved vitamins, minerals, amino acids, bee pollen, herbs, and other ingredients promoted for everything from reducing fatigue and promoting weight loss to curing osteoporosis and AIDS.

¹² Schering Corp., Dkt. No. 9232 (Sept. 16, 1991) (initial decision).

¹³ *Id.* at 45-56, 69-71.

¹⁴ *Id.* at 65-66.

¹⁵ Live-Lee Productions, Inc./Ruta Lee, No. 9423058 (June 15, 1995) (consent agreement subject to final approval); Body Wise International, Inc., No. 9323077 (June 6, 1995) (consent agreement subject to final approval); National Dietary Research, Inc., D. 9263 (May 4, 1995) (consent agreement subject to final approval); Nature's Bounty, Inc., No. 9323224 (Apr. 27, 1995) (consent subject to final approval); Third Option Labs, Inc., No. 9423027 (Apr. 13, 1995) (consent subject to final approval); Home Shopping Network, Inc., D. 9272 (complaint issued Mar. 3, 1995); HealthComm, Inc., No. C94-5024 RJB (W.D. Wash. Jan. 19, 1995) (stipulated permanent injunction); *Bee-Sweet, Inc.*, C-3550 (Jan. 17, 1995) (consent); RN Nutrition, C-3549 (Jan. 13, 1995); *Schering*, Dkt. No. 9232 (initial decision) and (Nov. 4, 1994) (consent); *L & S Research*, C-3534 (consent); *FTC v. Redhead*, No. 93-1232-JO (D. Ore. June 20, 1994 & Sept. 9, 1994) (stipulated permanent injunctions); RN Nutrition, File No. 9123145 (Sept. 2, 1994) (consent agreement subject to final approval); Metagenics, Inc., Dkt. No. 9267 (complaint issued Aug. 19, 1994); United States v. General Nutrition, Inc., No. 94-686 (W.D. Pa. Apr. 28, 1994) (consent decree); *FTC v. Silueta Distributors, Inc.*, No. C-93 4141 BAC (N.D. Cal. July 11, 1994) (preliminary injunction); *FTC v. Nutrition Research & Marketing, Inc.*, No. 93-2031-PHX-RCB (D. Ariz. Oct. 21, 1993) (stipulated permanent injunction); *Nature's Cleanser, Inc.*, C-3450 (July 12, 1993) (consent); *Sharper Image Corp.*, C-3443 (June 28, 1993) (consent); *CC Pollen Co.*, C-3419 (Mar. 16, 1993) (consent); *The Winning Combination, Inc.*, C-3398 (Aug. 24, 1992) (consent); *Nu-Day Enterprises, Inc.*, C-3380 (Apr. 22, 1992) (consent); *FTC v. Amerdream Corp.*, No. 91-0505 PHX RCB (D. Ariz. Nov. 5, 1991) (permanent injunction); *FTC v. International White Cross, Inc.*, No. C-91-0377-TEH (N.D. Cal. Oct. 21, 1991) (stipulated permanent injunction); *Miles, Inc.*, 114 F.T.C. 31 (1991) (consent); *FTC v. Allied Int'l Corp.*, No. 90-0120 CBM (Kx) (C.D. Cal. Nov. 14, 1990) (stipulated permanent injunction); *American Life Nutrition, Inc.*, 113 F.T.C. 906 (1990) (consent); *TV Inc.*, 113 F.T.C. 677 (1990) (consent); *Nature's Way Prods., Inc.*, 113 F.T.C. 293 (1990) (consent).

In an extreme example,¹⁶ a dietary supplement was promoted with a self-diagnostic test in which consumers were asked whether they "feel fatigued most of the time;" "crave sugar, bread, beer or other alcoholic beverages;" "are irritable, easily angered, anxious or nervous;" "have trouble thinking clearly, suffer occasional memory loss, or have difficulty concentrating;" "had unexpected weight gain;" "had loss of sex drive;" or "used birth control pills."¹⁷ According to the promotion, those who identified themselves as having any six of these or similar symptoms were in need of the advertiser's yeast control tablet. It would seem that these advertisements envisioned a rather large target market.

An advertisement for a bee pollen supplement claimed that the product prevented breast tumors, diabetes, heart disease, and flu; increased sex drive; and protected against arthritis.¹⁸ In addition, the supplement allegedly was clinically proven to reduce skin sensitivity, soothe arthritis pain, and help with blood pressure, constipation, moles, colds, weight control, prostate disease, asthma, and hay fever. The marketers of this remarkably potent product presumably did not expect their advertising, which appeared in a widely disseminated Chinese-language newspaper, to capture the attention of the FTC.

When the FTC determines that advertisements convey false or unsubstantiated claims, it seeks administrative or federal district court orders prohibiting the misleading claims and providing other remedies. In appropriate cases, the Commission increasingly is seeking monetary relief. In April 1994, for example, the FTC announced a settlement with General Nutrition Corporation (GNC) that involved the payment of a \$2,400,000 civil penalty for the company's alleged violation of a prior FTC order.¹⁹ The action challenged the claims for forty-two different products advertised or sold by GNC (including mussel extract for arthritis; glucomannan, spirulina, and grapefruit extract for weight loss; various amino acids for muscle building; and sublingual vitamin B-12 to boost energy levels).²⁰ That case was followed in July 1994 by a \$1,400,000 settlement with L & S Research for allegedly deceptive claims regarding the weight loss and muscle building properties of products such as "Cybergenics," "Cybertrim," "Quicktrim," and "Mega Fat Burner."²¹

As suggested by the number and kind of cases recently brought against allegedly deceptively advertised dietary supplements, this area receives significant attention at the FTC. Many companies disseminate unsubstantiated and misleading claims for dietary supplements. This activity is problematic both for consumers, who are entitled to make purchasing decisions based on accurate, fully substantiated claims, and for the rest of the supplement industry, which must compete with those companies making allegedly violative claims. Due to its impact on the market, therefore, supplement advertising will continue to be an active component of the FTC's agenda.

IV. THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT

On the question of what effect the newly enacted dietary supplement legislation²² will have on the FTC's approach to regulating advertising claims, it is important to note

¹⁶ *Nature's Way*, 113 F.T.C. at 293.

¹⁷ *Id.*

¹⁸ *American Life Nutrition*, 113 F.T.C. at 906.

¹⁹ *General Nutrition*, No. 94-686.

²⁰ *Id.*

²¹ *L & S Research*, C-3534.

²² See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

that such a discussion necessarily is preliminary. Nevertheless, a general review of the topic is appropriate and some predictions may be offered.

First, as is the case with the Nutrition Labeling and Education Act (NLEA),²³ the new supplement legislation does not apply specifically to advertising, rather it is limited to labeling-related issues. The FTC, however, always has worked to maintain a consistent policy with the FDA regarding the regulation of claims on labeling and in advertising. This policy is reflected in the Enforcement Policy Statement on Food Advertising issued by the Commission in May 1994.²⁴ That policy statement sets forth the FTC's approach to health and nutrient-content claims in advertising, in light of the NLEA and the FDA's implementing regulations.²⁵ Harmonization between the two agencies in the area of dietary supplements will receive similar emphasis.

The DSHEA probably will not result in significant changes in the manner in which the FTC evaluates claims in the dietary supplement area, or in the types of cases brought. For health claims on supplement labels, the DSHEA retains the NLEA requirement of FDA pre-approval.²⁶ With respect to the evaluation of health claims in food advertising, the FTC's approach is as follows:

In evaluating health claims, the Commission looks to a number of factors to determine the specific level of scientific support necessary to substantiate the claim. Central to this analysis is an assessment of the amount of substantiation that experts in the field would consider to be adequate. The Commission regards the "significant scientific agreement" standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim. Thus, it is likely that the Commission will reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence.

The Commission also recognizes the importance of the petition process, established under the NLEA and FDA's regulations, as a mechanism for authorizing health claims in food labeling. The Commission will look with particular care at any health claims not specifically considered by the FDA in this process. The absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission's assessment of the adequacy of substantiation for the claim.

While the Commission's approach to evaluation of unqualified health claims will generally parallel FDA's assessment of whether there is significant scientific agreement supporting the relevant diet-disease relationship, the Commission recognizes that there may be certain limited instances in which carefully qualified health claims may be permitted under section 5 although not yet authorized by the FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support. At the same time, however, the Commission believes that qualified claims based on evidence that is inconsis-

²³ Pub. L. No. 101-535, 104 Stat. 2353 (1990).

²⁴ See 59 Fed. Reg. 28,388 (June 1, 1994).

²⁵ *Id.* at 28,390-96.

²⁶ NLEA § 403(r)(1)(B), 21 U.S.C. § 343(r)(1)(B)]; DSHEA § 403(r)(6), 21 U.S.C. § 343(r)(6).

tent with the larger body of evidence have the potential to mislead consumers, and, therefore, are likely to violate section 5.

The Commission recognizes the need to scrutinize closely qualified claims to maintain the credibility of health claims in food advertising and labeling. The Commission will therefore be especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community. In the absence of adequate qualification, the Commission will find such claims deceptive.²⁷

There is no reason to believe that this policy will not be applied equally to claims for dietary supplements.

Certain other specific elements of the DSHEA are relevant to this discussion. The legislation evidences an intent to ensure that dietary supplements marketed to the American public are safe. Although the FTC does not directly regulate the safety of such products, either an unsubstantiated claim of safety or a failure to disclose any significant or unreasonable risk of adverse effects (under ordinary conditions of use or under conditions of use recommended or suggested in advertising) could constitute a violation of the FTC Act.²⁸

The DSHEA's section 5 provision on third-party literature also is noteworthy. While consistent with First Amendment²⁹ principles in that it does not allow government regulation of the content of books or other forms of literature, the provision does recognize the government's right to prevent the deceptive marketing of products through promotional use of such materials.³⁰ This distinction is consistent with the Commission's approach to regulation in this area.³¹

A key element of DSHEA is section 6, which specifically allows dietary supplement labeling claims regarding classical nutrient-deficiency diseases or the effect of a nutrient or ingredient on human structure or function.³² These claims are permitted, provided the manufacturer of the product "has substantiation that such statement is truthful and not misleading."³³ This statutory substantiation requirement for manufacturers' labeling claims is similar to the FTC's substantiation requirement that applies to advertisers generally.³⁴ Thus, although the DSHEA allows this category of claims on labeling for dietary supplements without prior FDA approval, it should not be seen as creating a "free fire zone" for such claims. The Commission's cases stand for the proposition that health-related advertising claims — both express and implied — must not be

²⁷ Enforcement Policy Statement, 59 Fed. Reg. at 28,393-94 (footnotes omitted).

²⁸ See, e.g., *Nature's Cleanser*, C-3450 (consent); *Consumer Direct, Inc.*, 113 F.T.C. 923 (1990) (consent); *Allied Int'l Corp.*, No. 90-0120 CBM (Kx) (stipulated permanent injunction); *North American Philips Corp.*, 111 F.T.C. 139 (1988).

²⁹ U.S. CONST. amend. I.

³⁰ DSHEA § 403B, 21 U.S.C. § 343B.

³¹ See *Advertising in Books*, Enforcement Policy, 36 Fed. Reg. 13,414 (1971) ("mirror image doctrine"); *Perma-Maid Co. v. FTC*, 121 F.2d 282 (6th Cir. 1941) (stainless steel cookware distributor's use of pamphlets written by third party including inaccurate statements regarding health hazards of aluminum cookware held actionable under FTC Act). *Compare Scientific Mfg. Co. v. FTC*, 124 F.2d 640 (3d Cir. 1941) (sale and distribution of pamphlets at issue in *Perma-Maid* not actionable under FTC Act where seller/distributor has no interest in manufacture, sale, or distribution of cookware).

³² DSHEA § 403(r)(6), 21 U.S.C. § 343(r)(6).

³³ *Id.*

³⁴ See *Substantiation Statement*, 104 F.T.C. at 839.

misleading and must be substantiated by competent and reliable scientific evidence before they are disseminated. The DSHEA does not alter or diminish these requirements.

V. CONCLUSION

As demonstrated by the cases cited herein, health related claims for dietary supplements have been the subject of a considerable number of FTC actions. The agency evaluates advertising claims for supplements by applying the same criteria used in reviewing advertising generally. Claims must be truthful and adequately substantiated. The review of advertising for supplements, under these criteria, will continue to be an important component of the FTC's advertising enforcement program.