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Affecting FDA-Regulated Products*

Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission and National Advertising Division

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I. INTRODUCTION

The changing regulatory landscape continues to present challenges to marketers of dietary supplements. Federal, state and even local regulators continue to bring enforcement actions against supplement marketers, alleging that the companies' marketing practices were deceptive or unfair. This article provides insight into the current regulatory environment and discusses the law relevant to specific types of claims.

Under a liaison agreement,¹ the Federal Trade Commission (FTC) acts as the primary regulator of dietary supplement advertising and the Food and Drug Administration (FDA) possesses primary enforcement responsibility for dietary supplement claims made in "labeling." In addition to the FTC and FDA, the National Advertising Division (NAD) of the Council of Better Business Bureaus, Inc. (CBBB) plays an active role in shaping dietary supplement advertising. The NAD is an industry-funded, self-regulatory body that reviews nationally disseminated advertising for truth and accuracy.² The NAD's cases result from 1) challenges by marketers to competitors' advertising, and 2) advertising monitoring by NAD staff.³ The NAD's decisions are not binding on the FTC.⁴ Nonetheless, an advertiser's compliance or non-compliance with an NAD decision may influence the course of FTC enforcement action.⁵

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¹ FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH) ¶ 9851 (1971).

² Membership fees paid by businesses to the (CBBB) provide the sole source of funding for the NAD. Press Release, NAD, NAD Refers Advertising for Bioforce USA 'Sanhelious Curbita Bladder Caps' to Government (Oct. 29, 2007), www.nadreview.org/default.asp?SessionID=1269346&DocType=1&CaseType=1. The National Advertising Review Board (NARB) provides appellate review of NAD cases. *Id.* Like the NAD, the NARB is a self-regulatory body that is funded solely by CBBB membership fees. *Id.* Another entity, the National Advertising Review Council (NARC) establishes the policies and procedures for both the NAD and the NARB. *Id.* The Association of National Advertisers, Inc. (ANA), the American Association of Advertising Agencies, Inc. (AAAA), the American Advertising Federation, Inc. (AAF) and the CBBB created the NARC in 1971. *Id.* The NARC also establishes policies and procedures for two additional, specialized advertising self-regulatory bodies, the Children's Advertising Review Unit (CARU) and the Electronic Retailing Self-Regulation Program (ERSP). *Id.*

³ *Id.*

⁴ See *Stouffer Foods Corp.*, 118 F.T.C. 746, 818 n. 5 (1994) ("Although the Commission often agrees with the decisions of industry self-regulatory organizations such as NAD regarding whether particular claims are misleading, the decisions of such organizations are not controlling in cases before the Commission").

⁵ See Press Release, FTC, Dietary Supplement Advertiser Settles FTC Charges of Deceptive Health Claims (May 12, 1998) (announcing complaint against maker of Cholestaway dietary supplement; "In 1995, according to the FTC, the Council of Better Business Bureau's National Advertising Division (NAD)—the advertising industry's self-regulatory arm—investigated the Cholestaway claims and determined that several were unsubstantiated. . . . The following year NAD submitted the matter to FTC, after finding that the company's revised ads did not adequately address a number of NAD's concerns regarding the truthfulness and accuracy of the advertising"); Letter from Mary K. Engle, Associate Director, Division of Advertising Practices, FTC, to Al Pope, President & CEO, United Egg Producers (Sept. 30, 2005) (closing deceptive advertising investigation of United Egg Products (UEP) because UEP planned to modify its advertising to "directly address the deception identified" in a NARB decision). In general, the FTC considers the NAD to be a role-model for self-regulation. See, e.g., Pamela Jones Harbour, Keynote Address at National Advertising Division Meeting (Sept. 26, 2005) (transcript available at <http://www.ftc.gov/speeches/harbour/050926selfreg.pdf>); Deborah Platt Majoras, Address

In particular, if an advertiser either refuses to cooperate with NAD proceedings or fails to comply with an NAD decision, the NAD has the power to refer cases to the FTC,⁶ and the FTC tends to give the referred cases high priority.⁷

Like the FTC, the NAD has taken a particular interest in dietary supplement advertising in recent years. In fact, the NAD recently partnered with the Council for Responsible Nutrition (CRN), a prominent dietary supplement trade organization, to expand its review of dietary supplement advertising. In a series of grants totaling almost half a million dollars over three years, the CRN will provide the NAD with an additional attorney whose sole focus will be dietary supplement regulation.⁸

In determining what advertising is permissible, dietary supplement advertisers are well-advised to consider not only FTC precedent and guidance but also NAD decisions on particular types of dietary supplement claims and advertising practices. This article 1) briefly reviews the regulatory framework for dietary supplement advertising, and 2) provides analysis of specific dietary supplement claims that have garnered FTC and NAD scrutiny in recent years.

II. REGULATORY FRAMEWORK FOR DIETARY SUPPLEMENT ADVERTISING

A. FDA and FTC's Shared Jurisdiction Over Dietary Supplement Marketing

The FTC and FDA share “complimentary jurisdiction” over dietary supplement marketing.⁹ Under their liaison agreement, the FTC possesses primary enforcement

Before the Council of Better Business Bureaus, Inc. 10 (Apr. 11, 2005) (transcript available at <http://www.ftc.gov/speeches/majoras/050411selfregorgs.pdf>) (“The Commission has previously cited NAD, which monitors general national advertising, as a model of real and meaningful self-regulation. NAD’s association with the CBBB provides a level of independence and objectivity. Its process is transparent, and its decisions are public. Significantly, it has a high level of support within the advertising industry, enjoying over 90% compliance with its decisions”) (internal citations omitted).

⁶ See NAD, CARU and NARB Policies and Procedures §§ 2.10(B) (allowing referral “to the appropriate government agency” if an advertiser fails to “file a substantive written response” within 30 days of receiving an NAD complaint); 2.9(B) (allowing referral of a case to “the appropriate government agency for review and possible law enforcement action” if an advertiser fails to submit a timely “Advertiser’s Statement” following a negative NAD decision); 3.7(B) (allowing referral of the “full record on the case . . . to the appropriate government agency” if NAD issues a negative decision and within “a time period appropriate to the circumstances of the case,” the advertiser fails to indicate that it will modify or withdraw advertisements); 4.1(B) (allowing referral of a case file “to the appropriate agency” if an advertiser refuses to provide a status report on compliance and continues disseminated unmodified advertisements following a negative NAD decision); 4.1(C)(b)(2) (allowing referral to “the appropriate government agency” if an advertiser refuses to respond to or comply with NAD compliance findings following a negative NAD decision).

⁷ See *supra* note 5; see also Pamela Jones Harbour, Keynote Address at National Advertising Division Meeting (Sept. 26, 2005) (transcript available at <http://www.ftc.gov/speeches/harbour/050926selfreg.pdf>) (noting that FTC takes NAD referrals “very seriously”) (citing Press Release, FTC v. Bogdana (May 12, 1998) (Jodie Bernstein, then Director of the FTC’s Bureau of Consumer Protection, noted “I am especially concerned that the advertisers continued to make deceptive claims even after the advertising was challenged by the [NAD]. The Commission staff supports the self-regulatory process and has worked with the dietary supplement industry to educate members about the truth-in-advertising requirements. But, as this case illustrates, when self-regulation fails, we are prepared to take action”), <http://www.ftc.gov/opa/1998/05/bogdana.htm>); Press Release, ERSP Refers Ultimate HGH Infomercial to the FTC (Sept. 10, 2004), <http://www.narcpartners.org/reports/list.aspx>); Press Release, FTC Targets Bogus Anti-Aging Claims for Pills and Sprays Promising Human Growth Hormone Benefits (June 9, 2005) (settlement provides for up to \$20 million in consumer redress), <http://www.ftc.gov/opa/2005/06/greatamerican.htm>.

⁸ Press Release, National Advertising Division, NAD Reviews Advertising for Gelita Health Products (Apr. 26, 2007); Press Release, Council for Responsible Nutrition, CRN Launches Advertising Campaign Urging Supplement Companies to Support NAD Self-Regulatory Program: Partners with Industry Magazines to Help Clean Up Supplement Advertising (Apr. 30, 2007); Press Release, Council for Responsible Nutrition, CRN, NAD Initiative to Expand Review of Dietary Supplement Advertising: New Initiative to Target False and Misleading Advertising (Sept. 18, 2006).

⁹ FTC, 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, at 1 n. 1 (Aug. 27,

responsibility for dietary supplement advertising while FDA possesses primary enforcement responsibility for dietary supplement claims made in “labeling.”¹⁰ The difference between advertising and labeling is not always clear given that the courts have interpreted the term “labeling” broadly. According to the courts, “labeling” means not only “labels” in the usual sense, but also any visual, audio or other material that bears a strong contextual relationship to the product.¹¹ Nonetheless, “labeling,” in general, means materials distributed at the point of sale. The FTC’s Guide on dietary supplement advertising explains:

As applied to dietary supplements, FDA has primary responsibility for claims on product labeling, including packaging, inserts and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs and similar direct marketing materials.¹²

The fact of shared jurisdiction has some important implications for dietary supplement advertising. This article discusses these implications.

B. *FTC’s Regulation of Dietary Supplement Advertising*

The Federal Trade Commission Act (FTC Act) prohibits false and deceptive advertising.¹³ As mentioned above, the FTC is the leading regulator for dietary supplement advertising. The FTC has actively pursued dietary supplement advertising cases since at least 1983, and it has launched numerous health-related enforcement campaigns that have led to consent orders against dietary supplement advertisers.¹⁴

1998) (comments submitted to FDA as part of FDA’s rulemaking on structure/function claims) (citing FTC-FDA Liaison Agreement, 4 Trade Reg., Rep. (CCH) ¶ 9851). “Although the Liaison Agreement does not refer explicitly to dietary supplements, the two agencies follow the same division of roles for dietary supplements . . .” *Id.*

¹⁰ *Id.*

¹¹ See 21 U.S.C. § 321(m) (“The term ‘labeling’ means all labels and other written, printed, or graphic matter 1) upon any article or any of its containers or wrappers, or 2) accompanying such article”); *Kordel v. United States*, 335 U.S. 345, 350 (1948) (“One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant”)

¹² FTC, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 1 (1998).

¹³ See FTCA §§ 5(a), 12; 15 U.S.C. §§ 45(a), 52. See also Letter from James C. Miller III, FTC Chairman, to John D. Dingell, Chair of House Committee on Energy and Commerce (Oct. 14, 1983) (“FTC Deception Policy Statement”), reprinted in 4 TRADE REG. REP. (CCH) ¶ 13,205, <http://www.ftc.gov/bcp/policysmt/ad-decept.htm>; FTC, FTC Advertising Substantiation Policy Statement, appended to *Thompson Medical 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), <http://www.ftc.gov/bcp/guides/ad3subst.htm>.

¹⁴ See FTC, Dietary Advertising Cases 1984-July 15, 2003, <http://www.ftc.gov/bcp/reports/di-etadvertisingcases.shtm>; Press Release, FTC, Operation Cure-All Wages New Battle in Ongoing War Against Internet Health Fraud (June 14, 2001) (“[S]ix new FTC enforcement actions target companies marketing a variety of devices, herbal products and other dietary supplements to treat or cure cancer, HIV/AIDS, arthritis, hepatitis, Alzheimer’s, diabetes and many other diseases. . . . Today’s announcement . . . marks the fourth group of targeted enforcement actions to address marketing of unproven health products on the Internet”); Press Release, FTC, FTC Launches “Big Fat Lie” Initiative Targeting Bogus Weight-Loss Claims (Nov. 9, 2004) (“Today, the [FTC] is launching “Operation Big Fat Lie,” a nation-wide law enforcement sweep against six companies making false weight-loss claims in national advertisements . . . The cases announced today challenge ads containing false . . . claims for a variety of products, including pills, powders, green tea, topical gels and diet patches”); Press Release, FTC, FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatment (Oct. 19, 2006) (announcing that FTC and FDA sent a total of 108 warning letters to dietary supplement marketers and other companies making false, deceptive or otherwise illegal diabetes claims).

In general, in order to comply with the FTC Act, dietary supplement advertisers must ensure that advertising is truthful, non-misleading and substantiated at the time of dissemination.¹⁵ Adequate substantiation for dietary supplement claims generally consists of a reasonable basis based on competent and reliable scientific evidence.¹⁶

The case of *In re Pfizer Inc.*¹⁷ sets forth the requirement articulated in cases under Section 5 of the FTC Act¹⁸ that advertisers must have a reasonable basis for making objective claims before the claims are disseminated. Under *Pfizer*, if no specific level of substantiation is claimed, what constitutes a reasonable basis is determined on a case-by-case basis by analyzing six factors:

1. The type of claim;
2. The benefits if the claim is true;
3. The consequences if the claim is false;
4. The ease and cost of developing substantiation for the claims;
5. The type of product; and
6. The level of substantiation experts in the field would agree is reasonable.¹⁹

The FTC defines the term “competent and reliable scientific evidence” to include any “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.”²⁰ The FTC has underscored that “[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration.”²¹

In agency guidance, the FTC has generally taken the position that studies on individual ingredients may be insufficient to substantiate claims for combination products if “there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients.”²² Agency guidance provides an example of a situation that presents reasonable suspicions regarding ingredient interactions; the Commission suggests that where “the combination of two herbs with similar stimulant properties could produce a stronger cumulative stimulant effect that might present safety hazards,” testing of the specific combination of ingredients may be appropriate.²³ In litiga-

¹⁵ DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 3.

¹⁶ DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 3 (“The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with .competent and reliable scientific evidence . . .”).

¹⁷ *In re Pfizer Inc.*, 81 F.T.C. 23 (1972).

¹⁸ 15 U.S.C. § 45.

¹⁹ *In re Pfizer Inc.*, 81 F.T.C. 23.

²⁰ See, e.g., DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 9; *United States v. Bayer Corp.*, Civ. Action No. 01-01 (HAA), 2 (D.N.J. Jan. 3, 2007) (consent decree following investigation of Bayer’s One-A-Day Weight Smart multi-vitamins; providing same definition for “competent and reliable scientific evidence”); *In the Matter of Goen Technologies*, FTC Docket No. C-4185 (Feb. 8, 2007) (consent order involving TrimSpa weight loss dietary supplements; providing same definition for “competent and reliable scientific evidence”).

²¹ DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 9 (emphasis added).

²² See FTC, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 17; see also *Id.* 16 (“Advertisers should make sure that the research on which they rely is . . . relevant to the specific product being promoted and to the specific benefit being advertised. Therefore, advertisers should ask questions such as: . . . Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study?”).

²³ *Id.*

tion, the FTC's position has been that testing on the entire product is required to address potential effects of interactions.²⁴ This presents practical difficulties, especially because dietary supplements, generally do not enjoy patent protection, and thus may not warrant the large expense of testing. As discussed more fully below, however, there is potentially room for claims based on competent and reliable testing on key ingredients, provided that the advertising includes careful disclosures about the basis for the claim.

The First Amendment protects truthful and non-misleading advertising claims.²⁵ This protection extends to claims based on competent and reliable testing of key ingredients.²⁶ For the First Amendment to apply, 1) the claims must be truthful and accurate, 2) the claims must not imply that the product, as opposed to an ingredient, was tested, and 3) the product must not include other ingredients that would negate the claims or pose a material safety risk.²⁷

In accord with First Amendment cases, the NAD has recognized that "[i]n the absence of direct testing on a product, an advertiser can make claims that are supported in the scientific community and are clearly limited to the ingredients, but must be careful to avoid making any express or implied product performance claims."²⁸

The practical effect is that key ingredient claims can, under certain circumstances, be made without substantial risk of regulatory action. The most important consid-

²⁴ In *FTC v. Enforma Natural Products, Inc.*, 362 F.3d 1204, 1217 (9th Cir. 2004), the Ninth Circuit rejected the FTC's argument that only double-blind testing of the particular product could substantiate a claim. Nevertheless, the FTC continues to argue that such a standard applies. Recently, FTC has relied upon *FTC v. Natural Solution, Inc.*, 2007 US Dist Lexis 60783, 6 (C.D. Cal. 2007), to argue that testing of the actual product formulation is required.

²⁵ See *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 564 (1980) ("The government may ban forms of communication more likely to deceive the public than to inform it . . . [Also, the government may ban] commercial speech related to illegal activity . . . If the communication is neither misleading nor related to unlawful activity, the government's power is more circumscribed.") (internal citations omitted).

²⁶ See, e.g., *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (holding that the FDA erred when it banned an advertiser's health claims about certain ingredients in its dietary supplements, namely antioxidants, fiber and omega-3 fatty acids, where the government provided only a conclusory, unsubstantiated assumption that the claims have the potential to mislead consumers); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 13 (D.D.C. 2002) (granting a preliminary injunction in advertiser's favor and rejecting FDA's ban of an antioxidant-vitamin claim by a dietary-supplement advertiser where the claim was substantiated by "approximately one-third of the total evidence examined," such evidence was not qualitatively weaker than the evidence against the claim, and where the FDA merely assumed, but provided no evidence, that "an appropriate disclaimer would confuse consumers and fail to correct for deceptiveness"); *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001) (granting a preliminary injunction in advertiser's favor and rejecting FDA's ban of folic-acid health claims in connection with its multi-vitamin product where the FDA's reason for the ban was based only on its determination that the scientific literature was inconclusive about whether synthetic folic acid was superior to naturally-occurring food folate, and where, even if food folate was found later to be superior to synthetic folic acid by credible evidence, that the First Amendment requires the FDA to craft an appropriate disclaimer, rather than ban the claim).

²⁷ See *supra* n. 26.

²⁸ *Nestle USA, Inc.*, NAD Case Report No. 4214, 30 (Aug. 2004) (further holding that "the advertiser can continue to make limited claims regarding the benefits of DHA and ARA supplementation in its advertising, as long as those claims are clearly compositional in nature, and clearly convey that the claimed benefits are supported in the scientific community and not proven on its Good Start formula"); *Justice Direct Partners, Inc.*, NAD Case Report No. 4210, 4 (July 2004) ("NAD determined the evidence in the record is sufficient to support compositional claims for Alzare relating to DHEA, Yohimbe, tribulus, etc. as long as the advertising is properly qualified so that it 1) makes clear that these claims are compositional claims only and 2) does not imply that use of Alzare maintains or enhances sexual potency, stamina, increases penile size, etc."); *Wyeth Consumer Healthcare, Inc.*, NAD Case Report No. 4153, 8 (Feb. 2004) ("NAD found the advertiser's claim of absorption equivalence between calcium carbonate and calcium citrate to be substantiated"; the limited claim focused on the performance of certain ingredients and did not compare one vitamin product against another); *Wyeth Consumer Healthcare*, NAD Case Report No. 4200 (Nov. 2003) ("NAD determined that the advertiser's express claims about the scientific findings with respect to lycopene and cardiovascular health were meaningful to consumers, adequately substantiated and supported by competent and reliable scientific evidence.").

eration is that the key ingredient testing meets the competent and reliable standard. In addition, the advertiser must ensure that the claims do not imply that the product, as opposed to an ingredient, was tested, which can usually be accomplished with careful advertising copy and conspicuous disclosures. Finally, the product cannot contain any other ingredients that would negate claims or pose a material safety risk, which can usually be established through analysis by an independent and properly qualified expert.

C. FDA's Regulation of Dietary Supplement Advertising

As described above, FDA is the agency responsible for claims relating to dietary supplement products on product labeling, including packaging, inserts and other promotional materials distributed at the point of sale. The key legislation governing FDA's role with respect to dietary supplement claims is the Dietary Supplement Health and Education Act of 1994 (DSHEA).²⁹

DSHEA and FDA regulations allow four types of labeling claims: 1) health claims, 2) qualified health claims, 3) nutrition content claims, and 4) structure/function claims.³⁰ Health claims describe a relationship between a dietary supplement or ingredient and reduced risk of a disease or other health-related condition.³¹ Qualified health claims are similar but discuss emerging evidence linking a dietary supplement or ingredient and reduced risk of a disease or other health-related condition.³² "Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited."³³ Nutrient content claims expressly or impliedly characterize the level of a nutrient in a food, e.g., "only 200 mg of sodium," "fat free," "good source of fiber." Finally, structure/function claims 1) describe a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States, 2) describe the role of a dietary ingredient intended to affect the structure or function in humans, 3) characterize the documented mechanism by which a dietary ingredient acts to maintain such structure or function, or 4) describe the general well-being from consumption of a nutrient or dietary ingredient.³⁴

FDA must pre-approve health claims and qualified health claims.³⁵ Similarly, nutrient content claims must be authorized by FDA's regulations.³⁶ Structure function labeling claims, on the other hand, do not require pre-approval.³⁷ However, unlike health claims and qualified health claims, structure/function claims may not expressly or impliedly suggest that a dietary ingredient or supplement can cure,

²⁹ Public Law 103-417 (1994). This article covers only portions of FDA law and regulation that are particularly relevant to dietary supplement advertising. Other areas of FDA regulation, such as dietary supplement formulation and manufacturing, are beyond the scope of this article.

³⁰ HHS, FDA, CFSAN, CLAIMS THAT CAN BE MADE ON DIETARY SUPPLEMENTS AND CONVENTIONAL FOODS §§ I-III (Sept. 2003), <http://www.cfsan.fda.gov/~dms/hclaims.html>. In general, dietary supplement labels bearing claims must also bear nutrition labeling as well as a "statement of identity" identifying a product as a dietary supplement, a net quantity of contents statement, nutrition labeling (usually a supplement facts panel), an ingredient list and contact information for the manufacturer, packer or distributor. See 21 C.F.R. §§ 101.3(a); 101.105(a); 101.36, 101.4(a)(1); 101.5 (2007); see also HHS, FDA, CFSAN, A DIETARY SUPPLEMENT LABELING GUIDE § I (Apr. 2005).

³¹ A DIETARY SUPPLEMENT LABELING GUIDE § I.

³² *Id.*

³³ *Id.*

³⁴ 21 U.S.C. § 343(r)(6) (2000); 21 C.F.R. § 101.93(f) (2007); see also A DIETARY SUPPLEMENT LABELING GUIDE § VI.

³⁵ *Id.*

³⁶ A DIETARY SUPPLEMENT LABELING GUIDE § IV.

³⁷ See 21 U.S.C. § 343(r)(6) (2000); 21 C.F.R. § 101.93 (2007).

treat, mitigate or prevent disease.³⁸ Also, a prescribed disclaimer must accompany structure/function labeling claims, and dietary supplement companies must notify FDA of structure/function claims within 30 days of first marketing the product bearing such claims.³⁹ The prescribed structure/function claim disclaimer states: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”⁴⁰

DSHEA and FDA’s approach to various claims has several important implications for advertising. First, with regard to health claims, the FTC has stated that it “gives great deference to FDA determination of whether there is adequate support for a [claim].” Thus, for example, FTC may reject most unqualified advertising claims associating omega-3 fatty acids with reduced risk of coronary heart disease given that the FDA rejected an unqualified health claim for the same ingredient and disease risk.⁴¹ Similarly, FDA acceptance or rejection of qualified health claims and structure/function claims also may be important in predicting how the FTC may approach similar advertising claims. Importantly, however, FTC has indicated that although it aims to be consistent with FDA, “there may be certain limited instances when a qualified health claim in advertising may be permissible under FTC law [i.e., in advertising], in circumstances where it has not been authorized for labeling.”⁴²

FDA’s regulation of structure/function claims also impacts dietary supplement advertising.⁴³ In particular, even though DSHEA does not reach advertising, the FTC has taken the stance that the DSHEA disclaimer, which is required on labeling, may be necessary in some advertisements to prevent deception.⁴⁴

Finally, an important point for dietary supplement advertisers is that FDA has asserted jurisdiction over websites selling products as point of sale “labeling.”⁴⁵ Thus, dietary supplement claims appearing on such websites must comply with

³⁸ See 21 U.S.C. § 343(r)(6) (2000); 21 C.F.R. § 101.93(g) (2007); Final Rule on Structure/Function Claims, 65 Fed. Reg. 999 (Jan. 6, 1999) (providing numerous examples of illegal disease claims versus allowed structure/function claims that may be acceptable depending on surrounding context).

³⁹ See 21 U.S.C. § 343(r)(6) (2000); 21 C.F.R. § 101.93(a)-(e) (2007). Precise formatting is required for the structure/function claim disclaimer. See *id.* FTC guidance refers to this disclaimer as the “DSHEA disclaimer.” See DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 23-24.

⁴⁰ See 21 U.S.C. § 343(r)(6) (2000); 21 C.F.R. § 101.93(c). Section 101.93 requires specific formatting and placement for the structure/function claim disclaimer. See 21 C.F.R. 101.93(d), (e). Further, when accompanying multiple structure/function claims, the disclaimer must state: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” *Id.*

⁴¹ See Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Jonathan W. Emord (Sept. 8, 2004) (rejecting unqualified health claim associating omega-3 fatty acids with reduced risk of coronary heart disease), <http://www.cfsan.fda.gov/~dms/ds-ltr38.html>. In the same letter, FDA accepted, under certain conditions, a qualified health claim for omega-3 fatty acids and risk of coronary heart disease if a product meets certain conditions. *Id.* FDA’s stance on the qualified claim may influence FTC to accept similar qualified claims in advertising.

⁴² DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 2.

⁴³ See generally *U.S. v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D. N.J. 2004) (granting government summary judgment and entering injunction and restitution order for dietary supplement advertising found to violate FDCA), *aff’d*, 427 F. 3d 219 (3d Cir. 2005).

⁴⁴ DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 23-24.

⁴⁵ See Letter from Margaret M. Dotzel, Associate Commissioner for Policy, FDA, to Daniel J. Popeo and Paul D. Kamenar, Washington Legal Foundation (Nov. 1, 2001) (describing courts interpretations of “labeling” and concluding, “Accordingly, FDA believes that, in certain circumstances, information about FDA-regulated products that is disseminated over the Internet by, or on behalf of, a regulated company can meet the definition of labeling in section 201(m) of the FDCA. For example, if a company were to promote a regulated product on its website and allow consumers to purchase the product directly from the website, the website is likely to be ‘labeling.’ The website, in that case, would be written, printed or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product”); *U.S. v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d at 556-557, *aff’d*, 427 F. 3d 219 (3d Cir. 2005).

both 1) FTC's requirements that advertising claims are truthful, non-misleading and substantiated, and 2) FDA and DSHEA requirements for labeling claims.⁴⁶

D. FTC's Dietary Supplements Guide

In 1998, the FTC issued "Dietary Supplements: An Advertising Guide for Industry"⁴⁷ (the Guide) to assist the industry in ensuring truthful, non-misleading advertisements.

The Guide is divided into three principal sections. The first section discusses how the FTC identifies the claims conveyed by an advertisement. Particular attention is paid to identifying both express and implied claims since federal law prohibits advertisers from expressly or impliedly making deceptive or unsubstantiated claims. An advertisement can also be deceptive by failing to provide certain information in ads, and the Guide covers when and how advertisers should disclose qualifying information. Under laws enforced by the FTC, advertisers must have a reasonable basis for all express and implied product claims in an advertisement before disseminating it.⁴⁸

The second section explains how the FTC evaluates the adequacy of substantiation for advertising claims. This includes the amount and type of evidence, the quality of the evidence, the totality of the evidence and the relevance of the evidence to the specific claim. The third section covers consumer testimonials, expert endorsements and advertising claims based on historical or traditional use of supplements. It also addresses the relevance of certain specific provisions of DSHEA⁴⁹ to advertising.

The FTC has subsequently issued a guide for media entitled "Red Flag Bogus Weight-Loss Claims."⁵⁰ This guide provides examples of the most common false weight-loss claims and is intended to assist the media in identifying and declining to run such claims. According to the weight-loss guide, the most common false claims for weight-loss products are claims that a product will: 1) cause weight-loss of two pounds or more a week for a month or more without dieting or exercise; 2) result in substantial weight loss, no matter what or how much the consumer eats; 3) lead to permanent weight loss; 4) block the absorption of fat or calories to enable consumers to lose substantial weight; 5) safely enable consumers to lose more than three pounds per week for more than four weeks; and 6) cause substantial weight loss for all users, or cause substantial weight loss by wearing a device on the body or rubbing a product into the skin.⁵¹

Put simply, the FTC's position is that there is no such thing as a "Magic Pill" for weight loss, and that healthy weight loss can only be achieved through diet, exercise and portion control.⁵²

⁴⁶ See e.g., FDA Warning Letter from Alonzo E. Cruse, District Director, FDA, to James Kirby, Senior Partner/Founder, Redux Beverages, LLC (Apr. 4, 2007) (explaining, *inter alia*, that unapproved claims appearing on a website violate FDA laws and regulations by relating a dietary supplement with diseases); FDA Warning Letter from Joseph R. Baca, Director, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA, to Robert Held, Wellness Support Network (Oct. 12, 2006) (same).

⁴⁷ Available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.shtm>.

⁴⁸ See FTC Policy Statement Regarding Advertising Substantiation.

⁴⁹ 21 U.S.C. § 301 (2005).

⁵⁰ FTC, Red Flag Bogus Weight-Loss Claims (2003), available at <http://www.ftc.gov/bcp/online/edcams/redflag/resources.html>.

⁵¹ FTC, Red Flag Bogus Weight-Loss Claims, at 5.

⁵² See *id.*

III. CLAIMS THAT HAVE GARNERED FTC AND NAD SCRUTINY IN RECENT YEARS

A. Endorsements, Testimonials and Before-and-After Photographs

The FTC's "Guide Concerning Use of Endorsements and Testimonials in Advertising" (the "Endorsement Guide") provides that when an advertisement represents that an endorser used the advertised product, the endorser must have actually used the product at the time of the endorsement.⁵³ The Endorsement Guide further requires that endorsements "reflect the honest opinions, findings, beliefs or experience of the endorser."⁵⁴ In addition, an advertiser employing a consumer endorsement must have substantiation that the endorser's experience is representative of what consumers can expect to achieve, unless the advertisement discloses the actual generally expected performance or "disclose[s] the limited applicability of the endorser's experience."⁵⁵

The FTC has commented on the use of photographs depicting "before-and-after" consumer transformations in advertisements for dietary supplements. In its report "Weight-Loss Advertising: An Analysis of Current Trends," the FTC stated that some advertisers employ deceptive "before-and-after" pictures that present unbalanced comparisons.⁵⁶ The FTC explained that these images often include "before" pictures exhibiting "poor posture, neutral facial expression, unkempt hair, unfashionable attire, poor lighting and washed out skin tones," while the "after" pictures are "[b]rightly lit . . . [with a] smiling subject in fashionable, often skimpy, attire, shoulders held back, tummy tucked in, with a stylish hairstyle and carefully applied makeup."⁵⁷

Before employing consumer testimonials in advertisements, supplement marketers should confirm that the consumer providing the testimonial is actually using the product at the time of the endorsement or used it during the time indicated in the testimonial. An advertiser should also confirm that the consumer endorser's statements featured in the testimonial are based on the consumer's honest opinions and beliefs. Supplement marketers should ensure that the results claimed in the testimonial are representative of what consumers can expect to achieve or disclose in the advertisement either the typical performance or the limited applicability of the endorser's experience. Advertisers can disclose the limited applicability of the endorser's experience through statements such as "Results will vary," but this should not be considered an absolute safe harbor.⁵⁸ Where the results deviate

⁵³ 16 C.F.R. §§ 255.1(c), 2(b) (2006).

⁵⁴ *Id.* § 255.1(a).

⁵⁵ *Id.* § 255.2(a), *see also* FTC v. Garvey, 383 F. 3d 891, 900-905 (9th Cir. 2004) (discussing endorser, participant and direct participant standards).

⁵⁶ FTC, WEIGHT LOSS ADVERTISING: AN ANALYSIS OF CURRENT TRENDS, at 11-12 (2002), *available at* <http://www.ftc.gov/bcp/reports/weightloss.pdf>.

⁵⁷ *Id.* at 12.

⁵⁸ *See* 16 C.F.R. § 255.2(a). FTC's dietary supplement guidance states, "Vague disclaimers like 'results may vary' are likely to be insufficient." The guidance further provides an illustrative example demonstrating that such disclaimers are inappropriate where a testimonialist's results deviate significantly from what results consumers may typically expect:

An advertisement for a weight loss supplement features a before-and-after photograph of a woman and quotes her as saying that she lost 20 pounds in 8 weeks while using the supplement. An asterisk next to the quotation references a disclaimer in fine print at the bottom of the ad that reads, "Results may vary." The experience of the woman is accurately represented, but the separate, competent research demonstrating the efficacy of the supplement showed an average weight loss of only 6 pounds in 8 weeks. Therefore, the disclosure does not adequately convey to consumers that they would likely see much less dramatic results. The placement and size of the disclaimer is also insufficiently prominent to qualify the claim

significantly from what is considered typical, regulators are likely to consider the endorser's claim misleading.

Regarding "before-and-after" images, supplement advertisers should use photographs that present balanced comparisons. The "before" picture should be similar in quality and clarity to the "after" picture, and the pictures should display similar posture, facial expression and other physical attributes, apart from the bodily transformation.

B. "Up to" Claims

The FTC and the NAD have addressed claims touting a range of product performance or benefit, such as claims that a product provides "up to" a certain level of performance. Both the FTC and NAD have held that such claims require evidence that an "appreciable number" or "significant percentage" of consumers can achieve the upper limit of the range.⁵⁹ The NAD has indicated that studies showing that at least 10 percent of the subjects attained performance at the upper limit of the claimed performance range generally provide adequate support for the range claim.⁶⁰

When making "up to" or other performance range claims, supplement advertisers should have evidence showing that the upper limit of the range is typical and representative of what consumers can expect to achieve. Advertisers should not rely on outliers of study results; instead, they should have evidence demonstrating that at least 10 percent of the test subjects experienced the upper limit of the performance range. Given that NAD has suggested only that 10 percent may be an adequate approximation (rather than a replacement) for FTC's "appreciable number" standard, the actual number of consumers within this 10 percent category should also be "appreciable."⁶¹ That means that, if three subjects out of 10 realized the maximum benefit, it would probably not be enough to substantiate an "up to" claim, even though the 10 percent threshold has been met.

C. Percentage Claims

The FTC has voiced its concerns with performance claims that are expressed in percentages. In its report "Weight Loss Advertising: An Analysis of Current Trends", the FTC observed that percentage claims may be misleading if they suggest substantial performance results although the actual results are insignificant: "[A]

effectively. One approach to adequate qualification of this testimonial would be to include a disclaimer immediately adjacent to the quote, in equal print size that says, "These results are not typical. Average weight loss achieved in clinical study was 6 pounds." DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, at 19.

⁵⁹ See, e.g., *Plaskolite, Inc.*, 101 F.T.C. 344, 350 (1983) (requiring that "the maximum level of performance claimed can be achieved by an appreciable number of consumers under circumstances normally and expectably encountered by consumers"); *F.T.C. v. Rapaport Corp.*, Case No. C93 4038 VRW (N.D. Cal., Dec. 28, 1993) (stipulated permanent injunction); *Priceline.com, Inc.*, NAD Case Report No. 4073, 4, 17 (Aug. 4, 2003); *Cimo, Inc.*, NAD Case Report No. 3946 (Aug. 2, 2002); *Priceline.com*, NAD Case Report 3742, 2-3 (Mar. 30, 2001).

⁶⁰ See *Britesmile, Inc.*, NAD Case Report No. 4032 (Apr. 2, 2003) ("[W]ith respect to the [advertiser's] claim that 'With BriteSmile, your teeth can be up to 15 shades whiter' the fact that the advertiser may have one or two records on file showing that BriteSmile had whitened patients' teeth to this extent would not be sufficient to support the performance claim unless 'a significant percentage' of consumers experience such improvement (i.e., 10%).")

⁶¹ See *infra* note 67.

representation such as, ‘Clinical studies show people lost 300 percent more weight even without dieting,’ may cause consumers to conclude mistakenly that the clinically proven benefits are substantial, whereas, in fact, the difference between use of the product and dieting alone could be quite small (1.5 lbs. vs. .5 lbs.).”⁶² The report further explains that “[c]laims such as this one can be misleading because the difference in weight loss between the control and experimental groups in the study can be significant in percentage points, but very small in actual measurement or pounds.”⁶³

The FTC’s concern here is that consumers may be misled. Where a claim and disclosure accurately inform consumers, in a non-misleading way, of the average weight loss experienced by clinical trial subjects compared to placebo subjects (e.g., 15 lbs. versus 5 lbs), a 300 percent claim would not be misleading. The average difference between using the product and dieting alone in this example is 10 pounds a substantial difference that is outside of the FTC’s concern (i.e., that certain percentage claims suggest that the product will contribute to substantial weight loss when the supporting data show the difference to be “quite small.”).

D. *Safety Claims*

The FTC has been concerned with express or implied claims regarding the safety of dietary supplements. In several cases, such as *USA Pharmacal Sales, Inc.*,⁶⁴ *Western Botanicals, Inc.*,⁶⁵ *Gero Vita International, Inc.*,⁶⁶ the FTC required that advertising for certain dietary supplement products include specific warning statements, even though the FDA did not require such warnings. This was true for products containing ephedra or ephedrine alkaloids, yohimbe, androgen products, St. John’s wort, comfrey and others.

Supplement marketers should be aware of any potential safety risks that their products present, even if the FDA or other regulators has not documented such risks. Marketers should review scientific literature on the safety of the ingredients in their products, or commission or conduct studies on the ingredients’ safety. Even if an advertiser does not make express safety claims, regulators may take the position that a failure to disclose health risks renders an implied safety claim. Thus, all supplement marketers, regardless of whether they intend to make safety claims, should ensure their ads disclose any potential safety risks that are more than negligible, and have adequate substantiation for any express safety claims.

E. *Doctor Recommended, Approved, Formulated and Similar Claims*

Doctor-related claims such as “doctor recommended,” “doctor approved” and “doctor formulated” are generally held to high standards of substantiation. Claims that a doctor was involved in the development of a product (e.g., “doctor formulated”) require evidence showing that the doctor was actually involved to the extent claimed in the advertisement.⁶⁷ With respect to claims regarding the opinions of

⁶² FTC, WEIGHT LOSS ADVERTISING: AN ANALYSIS OF CURRENT TRENDS ix.

⁶³ *Id.* n. 34.

⁶⁴ FTC v. USA Pharmacal Sales, Inc. (M.D. 2003).

⁶⁵ FTC v. W. Botanicals, Inc. (E.D. Cal. 2001).

⁶⁶ FTC v. Gero Vita International, Inc., No. CV 03-3700-DT (C.D. Cal. 2005)

⁶⁷ See Iovate Health Scis., NAD Case Report No. 4653 (Apr. 10, 2007).

medical professionals (e.g., “doctor recommended” and “doctor approved”), the FTC requires competent and reliable survey evidence that a significant number of surveyed doctors actually expressed the claimed opinion.⁶⁸ In *Abbott Labs.*, the FTC alleged that the advertiser falsely claimed that its supplement product was recommended by doctors as a meal supplement and meal replacement.⁶⁹ According to the FTC’s complaint, the “doctor recommended” claims appeared in several advertisements that featured active, healthy adults, many of whom appeared to be in their thirties or forties.⁷⁰ The FTC alleged that, in the context of the ads, the doctor-related claims communicated that many doctors recommended the advertised product as a nutritional supplement for healthy adults, including those in their thirties and forties.⁷¹ The FTC found that a survey of doctors relied upon by the advertiser failed to substantiate the claims because it was not designed to determine whether many doctors actually recommended the product “as a meal supplement or replacement for healthy adults, as opposed to for adults who are ill or elderly and may have nutritional deficiencies.”⁷² According to the FTC, “the survey merely asked doctors to assume that they would recommend a supplement for adults who were not ill, and then to select the brand they would most recommend.”⁷³

The NAD has stated that it “closely scrutinizes [doctor opinion] claims and requires highly reliable supporting evidence as substantiation” because these claims carry great weight with consumers.⁷⁴ The NAD requires substantiation for doctor opinion claims in the form of “a random and statistically representative survey of doctors showing that a substantial percentage recommend the product and should be based on the actual experience of physicians in their ordinary practice.”⁷⁵

As support for its “doctor recommended” claims, the advertiser in *Garden Biotech, Inc.* relied on responses to follow-up questions that it asked doctors who received free samples of the advertiser’s dietary supplement product.⁷⁶ Over 30 percent of the doctors reported favorable results from their patients’ use of the product and requested additional samples.⁷⁷ In holding that the “doctor recommended” claims were unsubstantiated, the NAD stated that the responses to the advertiser’s follow-up questions did not constitute a “survey that establishes that the product is actually ‘recommended’ by [d]octors in the ordinary course of their practice.”⁷⁸

In *Lifekey Healthcare, Inc.*, the advertiser of a male enhancement supplement attempted to substantiate its “doctor recommended” claims through affidavits from individual physicians stating that they believed the supplement’s ingredients were safe.⁷⁹ But the NAD deemed these affidavits insufficient because they did not

⁶⁸ See Press Release, FTC, *Abbott Settles FTC Charges of Deceptive Claims for Its “Ensure” Nutritional Products* (Jan. 2, 1997), available at <http://www.ftc.gov/opa/1997/01/abbott.shtm>; *In re Abbot Labs.*, No. 962 3069 (1997).

⁶⁹ *In re Abbot Labs.*, No. 962 3069.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Pure Pharmaceuticals, LLC, NAD Case Report No. 4569 (Oct. 6, 2006); see also COUNCIL OF BETTER BUSINESS BUREAU’S, DO’S AND DON’TS IN ADVERTISING, § 19, ¶ 984 (1996) (“[A]dvertisers should avoid broad unqualified claims that a product is ‘doctor recommended’ unless they have strong supporting evidence because claims of this nature carry great weight with consumers.”).

⁷⁵ *Garden Biotech, Inc.*, NAD Case Report No. 4352 (June 29, 2005).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Lifekey Healthcare, Inc.*, NAD Case Report No. 4074 (July 31, 2003).

demonstrate that the physicians recommended the product to their patients for male enhancement in their actual medical practice.⁸⁰

F. *Fat Blockers and Carbohydrate Blockers*

Products that purportedly block the absorption of fat or carbohydrates have received considerable regulatory attention. FTC guidance makes clear the agency's position on fat blockers: "A claim is too good to be true if it says the product will . . . block the absorption of fat or calories to enable consumers to lose substantial weight."⁸¹ The FTC has emphasized that "[n]o fat blocker can block enough fat or calories to cause lots of weight loss. Even legitimate fat blockers must be used with a reduced-calorie diet to work."⁸² The agency has filed actions against marketers of purported fat blockers for making false and unsubstantiated claims regarding the fat-blocking efficacy of the products.⁸³ The FTC has also brought actions against makers of "carb" blocker products, alleging that the companies' claims that their products could block the absorption of carbohydrates were false and unsubstantiated.⁸⁴

On February 7, 2007, FDA approved the drug Orlistat as an over-the-counter weight loss aid for overweight adults. The drug is sold under the brand name Alli. FDA initially approved Orlistat as a prescription drug (Xenical) to treat obesity. The makers of Alli have advertised the product as a fat blocker. Some of the studies that the maker of Alli submitted to FDA as substantiation for the drug's efficacy have not been made public and may provide support for the fat-blocking claims. Nonetheless, claims that a supplement can obstruct the absorption of fat or carbs carry considerable risk. Marketers of such products should be prepared to draw scrutiny from regulators.

G. *Cold Prevention Products*

The FDA's structure/function rule provides a useful foundation for what types of cold claims may be made for dietary supplements.⁸⁵ The structure/function rule allows labeling claims that a product promotes a healthy immune system.⁸⁶ However, the rule prohibits more specific immunity claims that explicitly or implicitly point to a disease, such as colds or other viruses.⁸⁷ For instance, under the structure/function rule, FDA will allow the claim "supports the immune system," but it will not allow more specific claims such as "antiviral"⁸⁸ or "use this supplement during the cold and flu season."⁸⁹

The FDA's structure/function rule does not apply to non-labeling, advertising claims. Nonetheless, FTC and advertising self-regulatory entities have often

⁸⁰ *Id.*

⁸¹ See <http://www.ftc.gov/bcp/conline/edcams/redflag/sitemap.html>.

⁸² See *id.*

⁸³ *FTC v. Iworx*, No. 2:04-cv-00241-GCS (D. Me. 2005); *FTC v. No. 9068-8425 Quebec, Inc.*, No.: 1:02-CV-1128 (N.D.N.Y. 2003).

⁸⁴ See, e.g., *FTC v. Pinnacle Mktg., L.L.C.*, No. 04-cv-185-P-C (D. Me. 2004) ("Ultra Carb" dietary supplement); *FTC v. Direct-Prom, Inc.*, No. 04-cv-185-P-C (W.D. Tex. 2004) ("ReduCarb" dietary supplement).

⁸⁵ See 21 C.F.R. § 101.93.

⁸⁶ Final Structure Function Rule, 65 Fed. Reg. 999, 1029 (Jan. 6, 2000) (interpreting FDA's structure/function rule with regard to immunity claims).

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

found that while science supports numerous variations of healthy immune system advertising claims, cold prevention and treatment claims in advertising are likely unsubstantiated. In 2000, the FTC barred the makers of Cold Eeze from claiming that dietary supplement zinc lozenges “will prevent users from contracting colds” and “reduce the severity of cold symptoms.”⁹⁰

While properly substantiated immune support claims are of low risk, cold prevention and treatment claims for dietary supplements present a much higher risk of enforcement action.

H. Green Tea Weight and Fat Loss Supplements

While it may seem intuitive that a product shown to burn calories will lead to weight or fat loss, the FTC has taken the position that green tea has not been scientifically proven to be effective for weight or fat loss. The agency addressed green tea weight and fat loss claims in its “Operation Big Fat Lie” a nationwide law enforcement sweep that identified six companies allegedly making false weight-loss claims in national advertising.⁹¹ Several of these cases involved green tea-based dietary supplements. In particular, *United States v. Bayer Corporation*, involved weight management and increased metabolism claims for a multi-vitamin containing 32 mg epigallocatechin gallate (EGCG), a green tea extract.⁹² The FTC challenged the EGCG weight loss and metabolism claims as unsubstantiated and in violation of a previous order against Bayer.⁹³ Bayer agreed to pay a \$3.2 million civil penalty to settle the case.⁹⁴

In addition, the NAD has held that despite evidence showing that green tea can stimulate calorie-burning, studies submitted by advertisers do not show that green tea causes weight or fat loss.⁹⁵

I. Homeopathy

The medical theory of homeopathy is based on the belief that, if a large amount of a substance causes certain symptoms in a healthy person, smaller amounts of the same substance can treat those symptoms in someone who is ill. Homeopathic practitioners believe that the remedy must be so diluted as to make the active ingredient difficult or impossible to identify by analytical chemists. Homeopathy enjoys special protection under the Federal Food, Drug, and Cosmetic Act⁹⁶ (FDCA) because a homeopathic practitioner was one of the sponsors of the original food, drug and cosmetic law.

Products listed in the “Homeopathic Pharmacopeia of the United States”, a compendium of homeopathic standards and monographs recognized as official

⁹⁰ Quigley Corp., FTC Case No. 9823152 (Feb. 10, 2000) (“Decision & Order” following consent agreement). *But see* Matrixx Initiatives, Inc., NAD Case Report No. 4286 (Feb. 22, 2005).

⁹¹ See Press Release, FTC, FTC Launches “Big Fat Lie” Initiative Targeting Bogus Weight-loss Claims (Nov. 9, 2004), available at <http://www.ftc.gov/opa/2004/11/bigfatliesweep.htm>.

⁹² Complaint for Civil Penalties, Injunctive and Other Relief, Civ. Action No. 07-01 (HAA) (D.N.J. Jan. 3, 2007); Consent Decree, Civ. Action No. 07-01 (HAA) (D.N.J. Jan. 3, 2007).

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ See, e.g., ePharmacy/1-800-PATCHES.COM, NAD Case Report No. 4433 (Jan. 4, 2006), Irwin Naturals, NAD Case Report No. ___ (Sept. 13, 2007); see also SAN Corp., ERSP Report (2007) available at <http://www.narcpartners.org/reports/list.aspx>.

⁹⁶ 21 U.S.C. § 301 *et seq.*

under the FDCA,⁹⁷ may be sold without a new drug application and are exempt from good manufacturing practice requirements related to expiration dating and finished product testing for identity and strength. If a homeopathic drug claims to treat a serious disease such as cancer, it can be sold by prescription only. Only products sold for so-called self-limiting conditions such as colds, headaches and other minor health problems that eventually go away on their own, can be sold without a prescription. The FTC will still regulate claims that it deems to be false, misleading or lacking a reasonable basis.

Advertising of homeopathic products might benefit from the decision in *Pearson v. Shalala*, which provides that prominent disclaimers regarding the inconclusive nature of tests and studies supporting the product could be adequate to permit the sale of the product with curative claims.⁹⁸ However, that case also noted that “where evidence in support of a claim is outweighed by evidence against the claim, FDA could deem [the claim] incurable by a disclaimer and ban it outright.”⁹⁹ Thus, the FTC could ban the advertising of homeopathic products with certain curative claims.

J. *Muscle Builders*

The FTC has brought various cases against marketers of purported bodybuilding supplements, both because of safety concerns and because the marketers’ efficacy claims allegedly were not adequately substantiated. In cases brought against MET-Rx USA, Inc. and AST Nutritional Concepts, the FTC challenged claims for products containing androgen and other steroid hormones because of health risks posed by the products, including unwanted changes in male and female sexual characteristics and special dangers to persons at increased risk for prostate or breast cancer.¹⁰⁰ The FTC was particularly concerned that teenagers and athletes who were using the supplements as performance or muscle enhancers were being misled about their safety and potential negative side effects.¹⁰¹ The complaints alleged that marketers lacked adequate substantiation to support claims that the products were safe and produced no or minimal side effects.¹⁰²

Muscle-building products require a slightly different analysis, given the nature of the consumers who typically use these products. As both the FTC and NAD have held, the degree of sophistication of the target audience is a significant factor in determining the reasonable message conveyed by the advertising.¹⁰³ When advertising is targeted to a particular class of consumers, especially one with superior

⁹⁷ *Id.* §§ 321(g)(1), 351(b).

⁹⁸ 130 F. Supp. 2d 105, 113 (D.D.C. 2001).

⁹⁹ *Id.* at 10.

¹⁰⁰ Press Release, FTC, Androgen Supplement Marketers to Settle FTC Charges (Nov. 16, 1999), available at <http://www.ftc.gov/opa/1999/11/astmetrx.shtm>.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ See *In re Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 175-83 (1984); *In re Telebrands Corp.*, No. 9313, 2005 F.T.C. LEXIS 178, at *22 (Sept. 19, 2005) (“If an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience. Different target audiences come to an ad with different perceptions. Consumers cannot understand an ad or any communication without applying their own knowledge, associations or cultural understandings that are external to the ad itself. For that reason, the purpose of ad interpretation is to determine the claims that consumers particularly the target audience take away from an ad, whether or not an advertiser intended to communicate those claims. On the other hand, ad interpretation focuses on the impact of the particular ad on reasonable consumers in the target group; an advertiser is not liable for an interpretation of an ad that a consumer may have based on an idiosyncratic perspective.”); Nat’l Concrete Masonry Ass’n, NAD Case Report No. 4084 at 10 (Aug. 27, 2003) (acknowledging “reasonable member of the targeted class” standard).

knowledge of the product that is being advertised, the message conveyed is judged from the perspective of a reasonable member of that class.¹⁰⁴

The United States District Court for the Eastern District of New York has explained that bodybuilders are a sophisticated class of consumers for muscle-building supplements. In *Nature's Best, Inc. v. Ultimate Nutrition, Inc.*,¹⁰⁵ an unfair competition and trademark infringement suit brought under Section 43(a) of the Lanham Act, the court examined the level of sophistication of bodybuilders with respect to the whey protein nutritional supplements at issue in that case. After noting that the primary consumers of such products were bodybuilders, the court held that:

*These types of individuals are among the most sophisticated of consumers because they are conscientious in the nutrition choices that they make and carefully read labels. Courts have acknowledged that consumers selecting products or treatments that "affect their physical appearance and health" are "likely to exercise a great deal of care." Bodybuilders, for whom physical health and appearance are central to their livelihood, are certain to be conscious of the products they are selecting for consumption.*¹⁰⁶

Neither FTC nor NAD have addressed specifically whether bodybuilders are a sophisticated class of consumers. Prior decisions suggest that the NAD would consider bodybuilders to be sophisticated consumers with respect to muscle-building supplement advertising. In *PacificHealth Laboratories, Inc.*,¹⁰⁷ for example, the NAD recognized that print and Internet advertising for EnduroxR⁴ sports drink was targeted towards a particular class of endurance athletes and assessed the challenged claims from the standpoint of this "unique target audience."¹⁰⁸ In making that finding, the NAD agreed with the advertiser's position that the challenged advertisements appeared in magazines geared towards serious runners and swimmers such as *Runner's World*, *Running Times*, *Triathlete*, *Velo News*, and *Fitness Swimmer* a class of individuals with "superior athletic capabilities" recognizably distinct from recreational athletes.¹⁰⁹ Thus, "the typical consumer expectations against which the NAD assessed the accuracy of these [challenged] claims would be those" of the targeted audience.¹¹⁰

Accordingly, advanced bodybuilders are a sophisticated class of consumers of muscle-building supplements. Thus, regulators and arbiters of advertising disputes should be expected to evaluate advertisements that target this class consistently with how a reasonable advanced bodybuilder would interpret the claims.

¹⁰⁴ Nat'l Concrete Masonry Ass'n, NAD Case Report No. 4084, 10; Agriscience, NAD Case Report No. 3327, 6-7 (Aug. 1, 1996) ("NAD recognized that this promotional campaign was directed toward golf course superintendents, who are knowledgeable consumers capable of assessing their individual needs and determining which product was best suited for their situation. Therefore, in resolving this dispute, NAD defined its task as one of assessing whether the contested promotional materials contained sufficient information that would enable these educated consumers to make well-informed and prudent business decisions.").

¹⁰⁵ 323 F. Supp. 2d 429 (E.D.N.Y. 2004).

¹⁰⁶ *Id.* at 434 (internal citations omitted and emphasis added).

¹⁰⁷ NAD Case Report No. 3671 (July 1, 2000).

¹⁰⁸ *Id.* at 7.

¹⁰⁹ *Id.* at 5, 7.

¹¹⁰ *Id.* at 7. The NAD also has judged advertisements directed to golf course superintendents (Agriscience, NAD Case Report 3327), masons and builders, (Nat'l Concrete Masonry Ass'n, NAD Case Report No. 4084), and physicians and other professionals from the vantage of the reasonable consumer in those classes (*see* Novartis Consumer Health, Inc., NAD Case Report No. 3717, 9-10 (Jan. 1, 2001)).

IV. CONCLUSION

As more consumers find dietary supplements to be an accepted alternative to conventional medicine, regulators and competitors continue to step up efforts to scrutinize claims and substantiation. Certain types of dietary supplements as well as advertising techniques draw special attention from regulators. Marketers of dietary supplements should be keenly aware of the regulatory scheme applicable to supplement advertising. They should also identify high-risk business practices and carefully formulate their marketing strategies to avoid enforcement actions by regulators.