

ENFORCEMENT CORNER



Diet and Weight-Loss Ads Are Fat Targets for FTC Action

by John R. Fleder

It has been estimated that about 66 percent of U.S. adults are overweight or obese.¹ Food and beverage companies have responded by marketing a plethora of diet and weight-loss products, ranging from dietary supplements purporting to be “exercise in a bottle” to tea infused with ingredients that allegedly have fat-burning properties. The Federal Trade Commission (FTC) has recently devoted a large percentage of its consumer protection enforcement efforts to combat what it believes are rampant false and misleading claims about those products. Considering that current data suggest that our nation’s grapple with weight is only going to get worse,² we can expect to see even more diet and weight loss products, which means that we will likely see many more FTC enforcement actions against these types of products.

Weight-loss products have been among the highest priority targets for enforcement action by the FTC for years. In 1997, nine cases resulted from the FTC’s much publicized “Project Waistline,” a consumer education and law enforcement program targeting misleading and deceptive weight loss claims. A similar program called “Operation Big Fat Lie” followed in 2004, and resulted in six cases, including one against Natural Products, LLC and All Natural 4 U, LLC for making claims such as “Guarantees Rapid Weight Loss!” and “EAT ALL YOU WANT AND STILL LOSE WEIGHT (PILL DOES ALL THE WORK).”³

Recent FTC Activity

The FTC has stepped up its enforcement activity against weight-loss dietary supplements. In January 2007, the agency announced that the marketers of CortiSlim, Xenadrine EFX, TrimSpa, and One-A-Day WeightSmart settled FTC charges that the companies were making false or unsubstantiated weight loss and weight control claims. The claims for some of these products are what the FTC considers to be far-fetched and typical of the kinds of claims that the FTC has questioned in the past. For example, the marketers of CortiSlim

claimed that the product could cause rapid weight loss and reduce fat located in specific parts of the body.⁴ However, the claims for Bayer Corporation’s One-A-Day WeightSmart were comparatively innocuous: the company claimed that the product could “help you while you manage your weight” and could increase the users’ metabolism.⁵

Most of the claims that were attacked in these cases were based on the FTC’s assertion that the companies lacked adequate substantiation.⁶ Accordingly, in most instances, the orders provide that the companies cannot make specified claims “unless the representation is true, non-misleading, and, at the time it is made, [the companies] possess and rely upon competent and reliable scientific evidence that substantiates the representation.”⁷ However, in some instances, the FTC has absolutely prohibited certain claims, whether or not the advertiser has adequate substantiation.⁸

The FTC’s latest enforcement sweep reveals that the agency is paying close attention to the media hype on weight-loss products. One of the four products that was involved in the recent FTC actions touted the benefits of Hoodia gordonii, the very popular dietary ingredient from Africa, and two other products that heavily promoted green tea extract, or EGCG, which has almost become synonymous with alleged weight loss. The FTC will likely continue to monitor weight-loss ingredient fads and scrutinize the marketing of products containing the latest (and allegedly greatest) ingredients.

Claims Must Be Substantiated

Companies marketing diet or weight-loss products must have a sound understanding of the law governing the advertising of these products and, importantly, how the FTC’s regulation of these products differs from that of the Food

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and Drug Administration (FDA). For example, although the Dietary Supplement Health and Education Act (DSHEA) permits dietary supplements to be the subject of weight-loss claims, DSHEA does not automatically permit such claims in advertising. For advertising, companies must be sure to have data to substantiate their products' claims.⁹

The FTC regulates the advertising of diet and weight-loss products under its authority to prevent “unfair or deceptive acts or practices” under the Federal Trade Commission Act.¹⁰ Unlike FDA, the FTC does not generally regulate products based on their intended use (i.e., whether a product is intended to be used as a food or drug). Rather, FTC enforcement normally focuses on whether claims made for a product are truthful, nonmisleading, and substantiated by “competent and reliable scientific evidence.” Of crucial significance is that the FTC has repeatedly warned that companies must have adequate substantiation *before* they run an advertisement.¹¹ Thus, the FTC will generally reject a company's proof of substantiation unless the company can show that it was in possession of the substantiation before the advertisement appeared.

“Competent and reliable scientific evidence” is typically defined as “tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has 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.”¹² In addition, the FTC normally expects a higher level of substantiation for claims relating to health or safety.¹³

The likely consequences of an FTC action are significantly worse than those of a typical FDA action, such as a Warning Letter. The FTC usually obtains consumer redress or disgorgement of profits, and assesses monetary penalties, in addition to a cease and desist order or injunction that compels the defendant to comply with the law in the future. Moreover, the FTC has successfully argued that consumer

redress may be based on total product sales revenue rather than be limited to the violator's profits. Also, the FTC may “fence in” a company, meaning that a company is restricted in the types of claims it may make for all of its products even though only one product was the subject of impermissible unsubstantiated claims.

Conclusion

Opportunities to market diet and weight-loss products continue to grow. Before jumping on the latest diet trend, however, companies must make sure that all diet and weight-loss product claims are supported by adequate substantiation. In addition, they should hire an expert to review the data supporting the claims to make certain that the claims will pass both FTC and FDA muster. ▲

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- ¹ Centers for Disease Control (CDC), National Center for Health Statistics, “Prevalence of Overweight and Obesity Among Adults: United States, 2003-2004,” http://www.cdc.gov/nchs/products/pubs/pubd/hestats/overweight/overweight_adult_03.htm.
- ² CDC, “Overweight and Obesity,” at <http://www.cdc.gov/nccddp/dnpa/obesity/index.htm>.
- ³ *FTC v. Natural Products, LLC*, No. SACV 04-1279 AHS (MLGx) (C.D. Cal. Oct. 28, 2005).
- ⁴ *FTC v. Window Rock Enterprises, Inc.*, No. CV-04-8190-DSF (JTLx) (C.D. Cal. Oct. 3, 2006) (stipulated final agreement and order for permanent injunction and settlement of claims for monetary relief as to defendant Stephen F. Cheng).
- ⁵ Complaint at 4, *United States v. Bayer Corp.*, No. 07-01 (HAA) (D.N.J. Jan. 3, 2007).
- ⁶ See, e.g., Complaint at 12, *In re Goen Technologies Corp.*, No. 042 3127 (Jan. 4, 2007).
- ⁷ *FTC v. Robert Chinery, Jr.*, No. 05-3460 (GEB), at 10 (D.N.J. Dec. 26, 2006).
- ⁸ *Id.* at 9.
- ⁹ Of course, FDA expects companies to have substantiation for all product claims. However, FDA rarely questions the support for weight loss product claims.
- ¹⁰ 15 U.S.C. §§ 45 & 52.
- ¹¹ FTC, Policy Statement Regarding Advertising Substantiation 2 (July 27, 1984).
- ¹² *In re Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998) (final order); see also *In re Thompson Medical Co.*, 104 F.T.C. 648 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987) (requiring two adequate and well-controlled clinical studies to substantiate certain drug claims).
- ¹³ See, e.g., *In re Novartis Corporation and Novartis Consumer Health, Inc.*, Docket No. 9279, Final Order, section I (May 13, 1999) (“For purposes of ... this Order, ‘competent and reliable scientific evidence’ shall include at least two adequate and well-controlled, double-blinded clinical studies.”).
- ¹⁴ The civil penalty in the Bayer case was \$3.2 million, apparently the “largest penalty for an order violation ever obtained by the FTC in a health case.” Deborah Platt Majoras, Remarks at the 50th Annual FDLI & FDA Conference (Apr. 12, 2007).
- ¹⁵ 15 U.S.C. §§ 45(b) & (l), 53(b), 57(b).
- ¹⁶ *See FTC v. Kuykendall*, 371 F.3d 745, 764-68 (10th Cir. 2004) (en banc) for a thorough discussion of the judicial decisions on this issue.
- ¹⁷ FDA injunction actions will also try to fence in the violator. However, FDA has commenced few of these cases, particularly in the “claims” area.