

---

## food industry lawflash

February 27, 2014

### FTC Cracks Down on False Advertising in Dietary Supplements

*Supplements making claims regarding diabetes, genetically customized nutritional benefits, and weight loss are slammed for false advertising.*

Recent Federal Trade Commission (FTC) enforcement activities—including a ruling by the U.S. District Court for the Northern District of California against the marketer of a diabetes treatment and settlements with marketers of genetically customized dietary supplements and weight-loss food and dietary supplement products—reflect a significant push by the FTC to crack down on unsubstantiated claims for dietary supplements and other health products. This recent activity serves as a reminder of the following for marketers of dietary supplements:

- They must have adequate substantiation in their files before making claims.
- “Adequate substantiation” for health claims likely means two double-blind, placebo-controlled, human studies with statistically significant results.
- Review and approval of promotional and labeling materials should be a formal, standardized process.
- Employees at all levels and agents engaged by the company should be aware of and trained on the importance of these principles.

#### Wellness Support Network Inc.

On February 19, the Northern District of California ruled that Wellness Support Network Inc. must pay \$2.2 million in restitution and issued a 20-year injunction forbidding the company’s owners from falsely advertising diabetes treatments. This ruling was the result of FTC Act violations stemming from online sales of “diabetes pack” and “insulin resistance pack” supplements.<sup>1</sup>

The FTC filed suit in 2010 against Wellness Support Network based on false and misleading advertising claims about their products’ ability to lower blood sugar levels and reduce dependency on insulin and other medications that treat diabetes. The court rejected Wellness’s assertion that First Amendment principles of commercial free speech were a defense, stating that relevant case law does not stand for the principle that “a manufacturer or seller of dietary supplements—or for that matter, any product—has a First Amendment right to make claims that are false or deceptive.”

#### Operation Failed Resolution

In early January, the FTC announced settlements with marketers of food, dietary supplements, and cosmetic products in “Operation Failed Resolution,” an initiative aimed at stopping deceptive weight-loss advertising claims.<sup>2</sup> As part of “Operation Failed Resolution,” the FTC reached four settlements with marketers of deceptive

---

1. *FTC v. Wellness Support Network*, No. 3:10-cv-4879 CJS (N.D. Cal. Feb. 19, 2014); Andrew Scurria, *FTC Bags \$2M False Ad Win Against Diabetes Supplement Co.*, *Law360* (Feb. 20, 2014), <http://www.law360.com/lifesciences/articles/511330/ftc-bags-2m-false-ad-win-against-diabetes-supplement-co->.

2. Press Release, FTC, *Sensa and Three Other Marketers of Fad Weight-Loss Products Settle FTC Charges in Crackdown on Deceptive Advertising* (Jan. 7, 2014), available at <http://www.ftc.gov/news-events/press-releases/2014/01/sensa-three-other-marketers-fad-weight-loss-products-settle-ftc>.

weight-loss products: Sensa Products, L'Occitane Inc., HCG Diet Direct, and LeanSpa. All four companies are barred from making weight-loss claims about dietary supplements, foods, or drugs unless they have two adequate and well-controlled human clinical studies supporting the claims.

As part of "Operation Failed Resolution," the FTC released an updated guidance document for spotting false weight-loss claims in advertising titled "Gut Check: A Reference Guide for Media on Spotting False Weight-Loss Claims."<sup>3</sup> The FTC also sent a letter to publishers and broadcasters to help them use the guidance to screen out deceptive diet ads and also encouraged them to train their staff on claims discussed in the "Gut Check" guidance.<sup>4</sup>

## Genetically Customized Nutritional Supplements

Separately, but on the same day as the announcements regarding "Operation Failed Resolution," the FTC announced its proposed settlement with GeneLink, Inc. and Foru International Corporation, marketers of genetically customized nutritional supplements.<sup>5</sup> The companies' marketing materials included claims that the products could compensate for an individual's genetic disadvantages (as determined by an assessment of DNA obtained from a swab of a consumer's cheek), including serious conditions like diabetes and heart disease. Additionally, claims for a skin serum product said that the effectiveness of the product was scientifically proven, citing a "double blind, randomized and controlled study" that apparently was based on Internet research.

Under the proposed settlements with the FTC, GeneLink and Foru are prohibited from claiming that a drug, food, or cosmetic will treat, prevent, or reduce the risk of any disease by modulating the effect of genes or will have any particular effect based on a person's customized genetic assessment unless the claim is true and supported by at least two adequate and well-controlled human clinical studies.

## Implications

These recent developments confirm the FTC's continuing and potentially increasing interest in taking enforcement action in the context of unsupported dietary supplement marketing claims. Manufacturers and marketers of dietary supplements, especially those that make weight-loss claims or that target special populations with their products, must be vigilant in ensuring that their claims are supported with credible scientific research and in promoting their products through reputable media outlets.

Although there is no express statutory requirement for two "adequate and well-controlled"<sup>6</sup> human clinical studies, the FTC and courts continue to signal that marketers will be held to this standard in the context of health claims, requiring rigorous clinical studies that support truthful statements about the results of the study in relation to the average consumer.

Thus, with few exceptions, health claims made for dietary supplements are deemed to require double-blind, placebo-controlled human subject studies. Moreover, the recent actions discussed above reinforce that the FTC requires a level of substantiation that is reasonably tailored to the specific claims being made.

---

3. Press Release, FTC, FTC Has Updated Guidance for Media Outlets on Spotting False Weight-Loss Claims in Advertising, (Jan. 7, 2014), available at <http://www.ftc.gov/news-events/press-releases/2014/01/ftc-has-updated-guidance-media-outlets-spotting-false-weight-loss>; Bureau of Consumer Prot. Bus. Ctr., Gut Check: A Reference Guide for Media on Spotting False Weight Loss Claims, <http://www.business.ftc.gov/documents/gut-check-reference-guide-media-spotting-false-weight-loss-claims> (last visited Feb. 26, 2014).

4. Letter from Jessica Rich, Dir., Bureau of Consumer Prot., FTC, to unspecified publishers and broadcasters (Jan. 7, 2013), available at <http://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-has-updated-guidance-media-outlets-spotting-false-weight-loss-claims-advertising/140107gutcheckletter.pdf>.

5. Press Release, FTC, Companies Pitching Genetically Customized Nutritional Supplements Will Drop Misleading Disease Claims (Jan. 7, 2014), available at <http://www.ftc.gov/news-events/press-releases/2014/01/companies-pitching-genetically-customized-nutritional-supplements>.

6. "Adequate and well-controlled" human clinical studies are defined to mean randomized human subject studies that (1) utilize valid endpoints generally recognized by experts in the relevant disease field; (2) are conducted by persons qualified by training and experience to conduct this type of study; (3) yield statistically significant results between groups; and (4) are conducted by persons qualified by training and experience.

# Morgan Lewis

The FTC’s “Gut Check” guidance and its January 7, 2014 letter to publishers and broadcasters also reflect a push to increase awareness about claims substantiation for dietary supplement advertisements at all levels of product promotion and marketing. This broad-brush approach supports the conclusion that a documented process for the review and approval of promotional and labeling claims should be implemented by manufacturers at all levels of production, even where the claims are made by advertisers they hire. Further, the wide-reaching nature of the FTC’s awareness campaign will likely trigger additional scrutiny from third parties, including consumers and competitors.

The FTC’s effort to target such a broad audience with its recommendations also may signal that it is looking closely at the role of publishers and broadcasters in propagating claims that are made on behalf of dietary supplement marketers, which stands to further complicate advertising strategies for manufacturers of dietary supplements.

## Contacts

If you have any questions or would like more information on the issues discussed in this LawFlash, please contact any of the following Morgan Lewis lawyers:

### Washington, D.C.

Alexis Reisin Miller  
Kathleen M. Sanzo

202.739.5390  
202.739.5209

[armiller@morganlewis.com](mailto:armiller@morganlewis.com)  
[ksanzo@morganlewis.com](mailto:ksanzo@morganlewis.com)

## About Morgan, Lewis & Bockius LLP

Founded in 1873, Morgan Lewis offers more than 1,600 legal professionals—including lawyers, patent agents, benefits advisers, regulatory scientists, and other specialists—in 25 offices across the United States, Europe, Asia, and the Middle East. The firm provides comprehensive litigation, corporate, transactional, regulatory, intellectual property, and labor and employment legal services to clients of all sizes—from globally established industry leaders to just-conceived start-ups. For more information about Morgan Lewis or its practices, please visit us online at [www.morganlewis.com](http://www.morganlewis.com).

This LawFlash is provided as a general informational service to clients and friends of Morgan, Lewis & Bockius LLP. It should not be construed as, and does not constitute, legal advice on any specific matter, nor does this message create an attorney-client relationship. These materials may be considered **Attorney Advertising** in some states. Please note that the prior results discussed in the material do not guarantee similar outcomes. Links provided from outside sources are subject to expiration or change. © 2014 Morgan, Lewis & Bockius LLP. All Rights Reserved.