

Can You Back That Claim Up? FTC Sends Nearly 700 Notices About Substantiating Product Claims

The Bottom Line

- As the FTC appears focused on seeking monetary penalties in response to product claims, brands and marketers should ensure that their practices are lawful.
- While a response to a Notice of Penalty Offenses is not required by the FTC, any entity receiving such notice should conduct a review of claims about the efficacy or performance of its products.

The FTC, using its Penalty Offense Authority under Section 5 of the Federal Trade Commission Act, has put approximately 670 companies on notice that they could incur significant civil penalties of up to \$50,120 per violation if they fail to adequately substantiate their product claims. Notices of Penalty Offenses Concerning Substantiation of Product Claims (Substantiation Notice) were sent to companies involved in the marketing of over-the-counter drugs, homeopathic products, dietary supplements, and functional foods.

Substantiating Health Claims

Through litigated cases and policy statements, the FTC has made clear that advertisers must have a reasonable basis to support objective product claims. Claims about the health or safety benefits of a product must be based on “competent and reliable scientific evidence.”

Generally, the amount and type of substantiation required to meet the “competent and reliable scientific evidence” standard depends on a number of factors, including the type of claim and the amount of substantiation that experts in the field believe is reasonable. In 1998, the FTC issued *Dietary Supplements: An Advertising Guide for Industry*, which stated that “as a general rule, well-controlled human clinical studies are the most reliable form of evidence,” but results obtained in animal and *in vitro* studies, as well as epidemiologic evidence, could be considered to support a dietary supplement claim.

However, in 2022, the FTC replaced the 1998 guidance with the *Health Products Compliance Guidance*, which applies to “any health-related product,” including dietary supplements, foods, over-the-counter (OTC) drugs, homeopathic products, devices, health equipment, diagnostic tests, and health-related apps. The new guidance states that “randomized, controlled human clinical trials (RCTs) are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims.” The guidance further states that animal and *in vitro* studies, while useful as supporting or background information, generally cannot substantiate health-related claims without confirmation by human RCTs. High-quality epidemiologic evidence can be used to substantiate a claim in those limited cases where it is considered an acceptable substitute for RCTs by experts in the field, and RCTs aren’t otherwise feasible.

Particularly as RCTs have been considered the gold standard – but not an absolute requirement – for health benefit claims, the new guidance appears to be a shift in FTC policy. While the *Health Products Compliance Guidance* does not have the force of law, the FTC expressly referenced the guidance in the Substantiation Notice.

Notices of Penalty Offenses Concerning Substantiation of Product Claims

A Notice of Penalty Offenses allows the FTC to seek civil penalties against a company that engages in conduct that it knows has been found unlawful in a previous FTC administrative order, aside from a consent order.

While the initial distribution of the Substantiation Notice was limited to companies making or likely to make health claims, the Substantiation Notice is **not limited to health claims** and applies to any marketer making claims about the efficacy or performance of its products. Cited deceptive acts and practices include:

- Making an objective product claim without having a reasonable basis at the time the claim is made, consisting of competent and reliable evidence;
- Making a claim relating to the health benefits or safety features of a product without possessing and relying upon competent and reliable scientific evidence that has been conducted and evaluated objectively by qualified persons and that is generally accepted in the profession to yield accurate and reliable results, to substantiate that the claim is true;
- Representing, expressly or by implication, that a product is effective in the cure, mitigation or treatment of any serious disease – including heart disease, cancer, arthritis and erectile dysfunction – without possessing and relying upon at least one human clinical trial of the

product that (1) is randomized, (2) is well controlled, (3) is double-blinded (unless the marketer can demonstrate that blinding cannot be effectively implemented given the nature of the intervention), (4) is conducted by persons qualified by training and experience to conduct such studies, (5) measures disease endpoints or validated surrogate markers and (6) yields statistically significant results;

- Misrepresenting the level or type of substantiation for a claim; and
- Representing that a product claim has been scientifically or clinically proven unless at the time the representation is disseminated, the advertiser possesses and relies upon evidence sufficient to satisfy the relevant scientific community of the claim's truth.

It is worth noting that the Substantiation Notice indicates that RCTs are required for claims about serious diseases - not for all health benefit claims. This may indicate that the FTC is taking a more flexible approach to the "competent and reliable scientific evidence" standard than indicated in the *Health Products Compliance Guidance*.

Importance of Compliance with Endorsement and Testimonial Guidelines

Recipients of the Substantiation Notice also received a copy of the previous [notice of penalty offenses regarding the use of endorsement and testimonials](#) (Endorsement Notice). [As we've discussed](#), misleading practices identified in the Endorsement Notice include:

- Falsely claiming an endorsement by a third party;
- Misrepresenting that an endorser is an actual user, a current user or a recent user;
- Continuing to use an endorsement without good reason to believe that the endorser continues to subscribe to the views presented;
- Misrepresenting that an endorsement represents the experience, views or opinions of users or purported users;
- Using an endorsement to make deceptive performance claims;
- Failing to disclose an unexpected material connection with an endorser; and
- Misrepresenting that the experience of endorsers represents consumers' typical or ordinary experience.

Note that the FTC's *Health Products Compliance Guidance* also discusses endorsements and testimonials. The guidance explains that consumer testimonials and expert endorsements do not provide a workaround from applicable substantiation requirements. In other words, a company cannot make health claims through testimonials and endorsements that would be deceptive or that could not be substantiated if made directly by the company. The company must also have appropriate evidence to support the claim and disclose the results that consumers should typically expect.

What This Means for Companies

The FTC is continuing to explore its enforcement options following [FTC v. AMG Capital Management, LLC](#), in which the Supreme Court restricted the FTC's ability to seek monetary penalties under Section 13(b) of the FTC Act. Last fall, the FTC issued several Notices of Penalty Offenses to thousands of companies, putting them on notice regarding misrepresentations by for-profit educational institutions about job and earnings prospects, misleading endorsements, and deceptive claims about money-making opportunities.

Keep in mind that receiving a Notice of Penalty Offenses is not an indication that the recipient has engaged in any wrongdoing. Additionally, the Notice of Penalty Offenses does not create any new obligations or requirements for recipients. However, if a recipient nonetheless engages in conduct that the FTC has previously found unlawful under Section 5 of the FTC Act, the recipient may be subject to substantial civil penalties.

In fact, the FTC has used its Penalty Offense Authority to obtain monetary penalties in recent enforcement actions. For example, the FTC used its Penalty Offense Authority to support a:

- Combined [\\$5.5 million civil penalty from Kohl's and Walmart](#) for violating the Textile Act when they had previously received a Notice of Penalty Offenses regarding the improper labeling and advertising of textile products.
- \$2.6 million penalty from DK Automation after the company continued to use deceptive earnings claims after they received Notices of Penalty Offenses regarding money-making opportunities and endorsements.
- \$1.7 million penalty from WealthPress for deceptive money-making claims (made after the company received a Penalty Offense Notice for money-making claims), as well as violations of the Restore Online Shoppers' Confidence Act.

For More Information

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