

FTC Sends Penalty Offense Notices to Nearly 700 Companies Regarding Product Claims Substantiation

Ioana Gorecki, John E. Villafranco

April 13, 2023

The FTC sent out [new penalty offense notices](#) to 670 companies today, warning them that failure to substantiate product claims could result in civil penalties of more than \$50,000. The companies also received copies of the FTC's previously-issued penalty offense notices regarding endorsements and testimonials. This represents the FTC's fourth round of penalty offense notices (previous notices involved [education practices](#), [money-making opportunities](#), and [endorsements](#)).

We've covered the FTC's use of its long dormant Penalty Offense Authority extensively in prior posts (see [here](#), [here](#), [here](#), [here](#), and [here](#)). In those posts, we noted several unanswered questions regarding the FTC's use of that authority, such as whether the FTC can use dated decisions from decades ago to justify civil penalties for first-time offenses occurring today; whether the facts and legal standards in place today are sufficiently similar to those present in these dated decisions to satisfy statutory requirements; and whether companies are afforded sufficient due process under an expansive use of this authority.

These questions remain outstanding today, as we have yet to see the FTC "put to its proof" by defending its interpretation of this authority in court. The only relevant activity we've seen so far has been in two recent settlements specifically referencing Penalty Offense Notices ([DK Automation](#) and [WealthPress](#)).

In today's warning letters, the FTC outlined another broad array of purportedly deceptive practices that the FTC has determined to be unfair or deceptive in prior administrative cases, including:

- making an objective product claim without a reasonable basis consisting of competent and reliable evidence;
- making a health benefits or safety features claim without competent and reliable scientific evidence that has been conducted and evaluated in an objective manner by qualified persons and that is generally accepted in the profession to yield accurate and reliable results, to substantiate that the claim is true;
- claiming that a product is effective in the cure, mitigation, or treatment of any serious disease 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 end points 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 without evidence sufficient to satisfy the relevant scientific community of the claim's truth.

These cited administrative orders focus on a wide variety of product claims, including the biodegradability of certain plastics (*ECM Biofilms*), efficacy of add-on braking systems, auto fuel-savings devices, and gasoline additives (*Auto. Breakthrough Scis.*, *Brake Guard Products*, *Cliffdale Assocs.*), efficacy of hair epilators (*Removatron*), superiority of microwave ovens (*Litton Industries*), efficacy of weight loss treatments (*Porter & Dietsch*), and health claims related to treatment of cancer, erectile dysfunction, heart disease, and other ailments (*POM Wonderful*, *Daniel Chapter One*, *Thompson Medical*, *Bristol-Myers Comp.*, *American Home Products*).

The notices further encourage companies to reference the FTC's recently released "Health Products Compliance Guidance," which – as we noted [here](#) – constitutes a sweeping overhaul of the 1998 dietary supplement guidance and a departure from the agency's prior, flexible interpretation of the "competent and reliable scientific evidence" standard.

We will be watching closely to see how the FTC uses these Penalty Offense Notices in future matters and settlements. In the meantime, we encourage all companies (not only the ones who received notices directly) to review claim substantiation and endorsement practices with an understanding that the FTC staff is continuing its efforts to impose a less-flexible substantiation standard and more stringent disclosure requirements.