

Notice of Penalty Offenses Concerning Substantiation of Product Claims

The Federal Trade Commission has determined that the following acts or practices used in the advertising or promotion of products are deceptive or unfair and are unlawful under Section 5(a)(1) of the Federal Trade Commission Act.

- It is an unfair or deceptive act or practice for an advertiser to make an objective product claim without having a reasonable basis, at the time the claim is made, consisting of competent and reliable evidence.<sup>1</sup>
- It is an unfair or deceptive act or practice for an advertiser to make 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 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.<sup>2</sup>
- It is an unfair or deceptive act or practice for an advertiser to represent 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 end points or validated surrogate markers, and (6) yields statistically significant results.<sup>3</sup>

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<sup>1</sup> *POM Wonderful, LLC*, 155 F.T.C. 1 (2013), *aff'd in part*, 777 F.3d 478 (D.C. Cir. 2015); *Daniel Chapter One*, 148 F.T.C. 832 (2009), *aff'd*, 405 Fed. App'x 505 (D.C. Cir. 2010); *Auto. Breakthrough Scis., Inc.*, 126 F.T.C. 229 (1998); *Brake Guard Prods., Inc.*, 125 F.T.C. 138 (1998); *Litton Indus., Inc.*, 97 F.T.C. 1 (1981); *Porter & Dietsch, Inc.*, 90 F.T.C. 770 (1977), *modified*, 605 F.2d 294 (7th Cir. 1979), *amendments to order*, 95 F.T.C. 806 (1980).

<sup>2</sup> *POM Wonderful, LLC*, 155 F.T.C. 1; *Daniel Chapter One*, 148 F.T.C. 832 (2009); *Auto. Breakthrough Scis., Inc.*, 126 F.T.C. 229; *Brake Guard Prods., Inc.*, 125 F.T.C. 138; *Porter & Dietsch, Inc.*, 90 F.T.C. 770.

<sup>3</sup> *POM Wonderful, LLC*, 155 F.T.C. 1; *Thompson Med. Co.*, 104 F.T.C. 648 (1984), 791 F.2d 189 (D.C. Cir. 1986).

- It is an unfair or deceptive act or practice for an advertiser to misrepresent the level or type of substantiation for a claim.<sup>4</sup>
- It is an unfair or deceptive act or practice to represent 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.<sup>5</sup>

<sup>4</sup> *ECM Biofilms, Inc.*, 160 F.T.C. 652 (2015), *aff'd* 851 F.3d 599 (6th Cir. 2017); *Auto. Breakthrough Scis., Inc.*, 126 F.T.C. 229; *Cliffdale Assocs.*, 103 F.T.C. 110 (1984); *Litton Indus., Inc.*, 97 F.T.C. 1; *Std. Oil of Cal.*, 84 F.T.C. 1401 (1974).

<sup>5</sup> *ECM Biofilms, Inc.*, 160 F.T.C. 652; *POM Wonderful, LLC*, 155 F.T.C. 1; *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989); *Bristol-Myers Co.*, 102 F.T.C. 21 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984); *Am. Home Prods.*, 98 F.T.C. 136 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982).



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