



United States of America  
FEDERAL TRADE COMMISSION  
Washington, D.C. 20580

## Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs

The Federal Trade Commission (FTC) is issuing this Policy Statement to provide guidance regarding its enforcement policy with respect to marketing claims for over-the-counter (OTC) homeopathic drugs. It applies only to OTC products intended solely for self-limiting disease conditions<sup>1</sup> amenable to self-diagnosis of symptoms and treatment.<sup>2</sup> The Commission believes this Policy Statement is appropriate in light of the burgeoning mainstream marketing of OTC homeopathic products alongside other OTC drugs.

The FTC's authority over disease and other health-related claims comes from Sections 5 and 12 of the FTC Act. Section 5, which applies to both advertising and labeling, prohibits unfair or deceptive acts or practices in or affecting commerce, such as the deceptive advertising or labeling of OTC drugs.<sup>3</sup> Section 12 prohibits the dissemination of false advertisements in or affecting commerce of food, drugs, devices, services, or cosmetics.<sup>4</sup> Under these provisions, companies must have a reasonable basis for making objective product claims, including claims that a product can treat specific conditions, before those claims are made.<sup>5</sup>

Homeopathy, which dates back to the late-eighteenth century, is based on the view that disease symptoms can be treated by minute doses of substances that produce similar symptoms when provided in larger doses to healthy people. Many homeopathic products are diluted to such an extent that they no longer contain detectable levels of the initial substance. In general,

In 1988, the Food & Drug Administration (FDA) issued a Compliance Policy Guide (CPG) entitled “Conditions Under Which Homeopathic Drugs May be Marketed,” which permitted marketers to distribute OTC homeopathic products without demonstrating their efficacy.<sup>7</sup> Under the CPG, only homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis of symptoms and treatment may be marketed OTC. The CPG requires that OTC homeopathic drugs be labeled as homeopathic and that their labeling display at least one major OTC indication for use.

The FTC Act does not exempt homeopathic products from the general requirement that objective product claims be truthful and substantiated.<sup>8</sup> Nevertheless, in the decades since the Commission announced in 1972 that objective product claims must be substantiated,<sup>9</sup> the FTC has rarely challenged misleading claims for products that were homeopathic or purportedly homeopathic.<sup>10</sup>

Efficacy and safety claims for homeopathic drugs are held to the same standards as similar claims for non-homeopathic drugs. As articulated in the Advertising Substantiation Policy

have been conducted and evaluated in an objective manner by qualified persons and [that] are generally accepted in the profession to yield accurate and reliable results.”<sup>12</sup> In general, for health benefit claims, particularly claims that a product can treat or prevent a disease or its symptoms, the substantiation required has been well-designed human clinical testing.<sup>13</sup>

For the vast majority of OTC homeopathic drugs, the case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the product’s efficacy. Accordingly, marketing claims that such homeopathic products have a therapeutic effect lack a reasonable basis and are likely misleading in violation of Sections 5 and 12 of the FTC Act.<sup>14</sup> However, the FTC has long recognized that marketing claims may include additional explanatory information in order to prevent the claims from being misleading. Accordingly, the promotion of an OTC homeopathic product for an indication that

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<sup>12</sup> See, e.g. *POM Wonderful LLC*, 155 F.T.C. 56, 193 (2013), *aff’d in part* 777 F.3d 478, 504-05 (D.C. Cir. 2015), *cert. denied* No. 15-525, 2016 U.S. LEXIS 2991 (May 2, 2016); *Telebrands Corp.*, 140 F.T.C. 278, 347 (2005), *aff’d*, 457 F.3d 354 (4th Cir. 2006); *Novartis Corp.*, 127 F.T.C. 580, 725 (1999), *aff’d*, 223 F.3d 783 (D.C. Cir. 2000); *Brake Guard Prods., Inc.*, 125 F.T.C. 138, 256 (1998).

<sup>13</sup> See, e.g. *POM Wonderful LLC*, 155 F.T.C. at 5-6 (requiring well-designed, well-conducted, double-blind, randomized controlled clinical testing to substantiate heart disease, prostate cancer, and erectile dysfunction prevention and treatment claims; also imposing such a requirement for all future disease claims), *aff’d in part*, 777 F.3d at 504-05 (affirming Commission holding that competent and reliable scientific evidence consisting of randomized, well-controlled human clinical testing is needed for disease-related claims but finding fencing-in order requirement of two such tests was not justified in this instance); see also *FTC v. Nat’l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1202-03 (N.D. Ga. 2008) (accepting undisputed expert testimony that erectile dysfunction claims require well-designed, placebo-controlled, randomized, double-blind clinical trials for substantiation); *FTC v. Direct Mktg. Concepts, Inc.*, 569h5d[a5 1 Tf [-0.004 (in)2(d-)]To2(

is not substantiated by competent and reliable scientific evidence may not be deceptive if that promotion effectively communicates to consumers that: (1) there is no scientific evidence that the product works and (2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts.<sup>15</sup> To be non-misleading, the product and the claims must also comply with requirements for homeopathic products and traditional homeopathic principles. Of course, adequately substantiated claims for homeopathic products would not require additional explanation.

Perfunctory disclaimers are unlikely to successfully communicate the information necessary to make claims for OTC homeopathic drugs non-misleading. The Commission notes:

- Any disclosure should stand out and be in close proximity to the efficacy message; to be effective, it may actually need to be incorporated into the efficacy message.
- Marketers should not undercut such qualifications with additional positive statements or consumer endorsements reinforcing a product's efficacy.
- In light of the inherent contradiction in asserting that a product is effective and also disclosing that there is no scientific evidence for such an assertion, it is possible that depending on how they are presented many of these disclosures will be insufficient to prevent consumer deception. Marketers are advised to develop extrinsic evidence, such as consumer surveys, to determine the net impressions communicated by their marketing materials.
- The Commission will carefully scrutinize the net impression of OTC homeopathic

In summary, there is no basis under the FTC Act to treat OTC homeopathic drugs differently than other health products. Accordingly, unqualified disease claims made for homeopathic drugs must be substantiated by competent and reliable scientific evidence. Nevertheless, truthful, non-misleading, effective disclosure of the basis for an efficacy claim may be possible. The approach outlined in this Policy Statement is therefore consistent with the First Amendment, and neither limits consumer access to OTC homeopathic products nor conflicts with the FDA's regulatory