

## FEDERAL TRADE COMMISSION

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

**AGENCY:** Federal Trade Commission.

**ACTION:** Commission policy statement.

**SUMMARY:** The Federal Trade Commission has issued an Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs. The Statement describes the level of substantiation that the Commission expects for marketing claims for over-the-counter (OTC) homeopathic drugs. It also recognizes that marketing claims for OTC homeopathic products for an unsubstantiated indication might be made non-deceptive by the inclusion of additional explanatory information that effectively communicates to consumers that there is no scientific evidence that the product works and that the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts.

**DATES:** The Commission announced the issuance of the Statement on November 15, 2016.

**FOR FURTHER INFORMATION CONTACT:** Michael Ostheimer (202-326-2699) or Richard Cleland (202-326-3088), Bureau of Consumer Protection, 600 Pennsylvania Avenue NW., Washington, DC 20580.

#### SUPPLEMENTARY INFORMATION:

### 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, homeopathic product claims are not based on modern scientific methods and are not accepted by modern medical experts, but homeopathy nevertheless has many adherents.<sup>6</sup>

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 Statement, advertisers must have "at least the advertised level of substantiation." Absent express or implied reference to a particular level of support, the Commission, in evaluating the types of evidence necessary to substantiate a claim, considers "the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts believe is reasonable."<sup>11</sup> For health, safety, or efficacy claims, the FTC has generally required that advertisers possess "competent and reliable scientific evidence," defined as "tests, analyses, research, or studies that 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>

<sup>9</sup> See *Pfizer, Inc.*, 81 F.T.C. 23, 62-64 (1972).

<sup>10</sup> See, e.g., Complaint, *FTC v. HCG Diet Direct, LLC*, No. 2:14-cv-00015-NVW (D. Ariz. Jan. 7, 2014) (stipulated judgment) (challenging weight-loss claims for purported homeopathic products); Complaint, *FTC v. Iovate Health Scis. USA, Inc.*, No. 10-CV-587 (W.D.N.Y. July 14, 2010) (stipulated judgment) (challenging claims that purported allergy-relieving product was homeopathic and effective); *Quigley Corp.*, No. C-3926, 2000 FTC LEXIS 24 (Feb. 10, 2000) (consent order) (challenging cold treatment and prevention claims for homeopathic products); *Levey*, 116 F.T.C. 885 (1993) (consent order) (challenging weight-loss and impotency treatment claims for purported homeopathic products).

<sup>11</sup> Advertising Substantiation Policy Statement, 104 F.T.C. at 840. These factors are known as the *Pfizer* factors, after the 1972 case, *supra* note 9, in which they were first enunciated.

<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

<sup>3</sup> Federal Trade Commission Act, 15 U.S.C. 45(a)(2).

<sup>4</sup> Federal Trade Commission Act, 15 U.S.C. 52.

<sup>5</sup> See Advertising Substantiation Policy Statement, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986) ("Advertising Substantiation Policy Statement").

<sup>6</sup> FTC Staff Report on the Homeopathic Medicine & Advertising Workshop (Nov. 2016).

<sup>7</sup> See CPG Sec. 400.400 Conditions Under Which Homeopathic Drugs May be Marketed (revised Mar. 1995), <http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074360.htm>.

<sup>8</sup> "[A] product that contemporary technology does not understand must establish that this 'magic' actually works. Proof is what separates an effect new to science from a swindle . . . [I]f a condition responds to treatment, then selling a placebo as if it had therapeutic effect directly injures the consumer." *FTC v. QT, Inc.*, 512 F.3d 858, 862-63 (7th Cir. 2008).

<sup>1</sup> A self-limiting disease condition is one that resolves spontaneously with or without specific treatment.

<sup>2</sup> This Policy Statement does not apply to the practice of medicine.

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 is not substantiated by competent and reliable scientific

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.*, 569 F. Supp. 2d 285, 303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010) (“it seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims”); *Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989) (requiring “adequate and well-controlled clinical testing” to substantiate claims for hair removal product); *Thompson Med. Co.*, 104 F.T.C. at 826 (requiring well-controlled clinical studies to substantiate certain analgesic drug claims). The Commission has also accepted numerous settlements that required randomized controlled clinical testing for disease treatment and prevention claims. See, e.g., *Brown*, 152 F.T.C. 466, 481–82 (2011) (consent order); *Nestlé HealthCare Nutrition, Inc.*, 151 F.T.C. 1, 13 (2011) (consent order); *Viral Response Sys., Inc.*, 115 F.T.C. 676, 691 (1992) (consent order).

<sup>14</sup> Although this Policy Statement is limited to OTC homeopathic products for the treatment of self-limiting disease conditions (ones that resolve spontaneously with or without specific treatment) amenable to self-diagnosis, marketing claims about the efficacy of homeopathic products not covered by this Policy Statement also are subject to the requirements to Sections 5 and 12.

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

<sup>15</sup> A statement that a product is based on traditional homeopathic theories might put some consumers on notice as to the basis of the product's efficacy claims. However, because many consumers do not understand what homeopathy is, the Commission does not believe that such a statement alone would adequately put consumers on notice that a product's efficacy claims are not backed by scientific evidence, and could, in fact, enhance the perceived credibility of the claim. Similarly, the Commission believes that a statement that a product's efficacy “has not been evaluated by the Food and Drug Administration” does not adequately address the potential lack of substantiation for a product's efficacy claims; dietary supplements bear a similar disclosure but FDA does require that dietary supplement label claims be supported by competent and reliable scientific evidence. Finally, the Commission believes that a simple statement that a product's efficacy is not supported by scientific evidence does not convey the truly limited basis for the efficacy claim and that, to avoid deceiving consumers, it is likely necessary to explain that it is not accepted by modern medicine.

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 advertising or other marketing employing disclosures to ensure that it adequately conveys the extremely limited nature of the health claim being asserted. If, despite a marketer's disclosures, an ad conveys more substantiation than the marketer has, the marketer will be in violation of the FTC Act.

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 scheme. It would allow a marketer to include an indication for use that is not supported by scientific evidence so long as the marketer effectively communicates the limited basis for the claim in the manner discussed above.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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