Don't Forget About FTC Compliance: Substantiating Claims to Avoid Misleading Consumers

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Life sciences companies regularly review their labeling and promotional materials to ensure compliance with Food and Drug Administration requirements. FDA makes its Warning Letters publicly available, and failure to correct unapproved, false, or misleading promotional materials can carry additional consequences. However, the Federal Trade Commission also reviews advertising for certain products, and consent orders by the Federal Trade Commission may be accompanied by serious financial penalties. This Bulletin is not intended to be a comprehensive look at FTC authority and actions, but we have provided a brief overview because we frequently see clients focus solely on FDA compliance when reviewing promotional materials.

Background

The FTC has primary jurisdiction to regulate the truth or falsity of advertising for cosmetics, over-the-counter drugs, non-restricted medical devices, and food (including dietary supplements).[1] FDA has primary jurisdiction to ensure products are not misbranded and to regulate labeling and prescription drug and restricted medical device advertising. Unlike FDA, the FTC evaluates claims for all products the same way: the advertising must be truthful (not deceptive) and fair and the claims must be substantiated.[2] Rather than focusing on the classification of the product, the FTC focuses on how reasonable consumers will interpret the advertising. Thus, whether a product is a dietary supplement, a cosmetic, a non-restricted medical device, or an OTC drug, the FTC will expect the company advertising the product to be able to substantiate the claims being made before they are made. Advertisers are responsible for "all reasonable interpretations" of the claims they make—if a claim is open to multiple interpretations, advertisers should be aware that they can be liable for reasonable misinterpretations by consumers.

For most objective promotional claims about a product, the FTC requires a "reasonable basis" to support the claim.[3] The FTC evaluates whether the advertiser has at least the level of substantiation claimed (expressly or impliedly) in an advertisement. If the advertiser claims that "tests show X," the FTC expects the advertiser to have tests showing X on file. When the advertisement does not reference a specific level of support, the FTC notes that consumers will expect that the advertiser still had a reasonable basis for making any claims. For health claims, the FTC requires a higher level of substantiation: "competent and reliable scientific evidence."[4] There is no magic number of studies required, but the standard has been defined in FTC case law as:

> tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.[5]

1 See http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm (last accessed 10/29/2016).
2 We will not discuss here the legal distinctions between "labeling" and "advertising," but examples can be found in 21 C.F.R. § 202.1.
3 See, e.g., https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation (last accessed (last accessed 10/29/2016).
4 See, e.g., https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf (last accessed 10/29/2016).
5 See http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm#ftnref7 (last accessed 10/29/2016).

Enforcement Action Examples

Manufacturers and advertisers should be aware that the FTC may take action even where FDA does not have guidelines in place. For example, in April 2016, four companies entered into settlements with the FTC for advertising their personal care products as "all natural" or "100% natural." FDA does not define "all natural,"[6] but the FTC reasoned the term was misleading in these instances because the products contained synthetic ingredients.[7]

In another case, the FTC prevailed against a juice company for making disease prevention claims about its products. Even though the company had conducted research to support the claims, the FTC evaluated the research as a whole, determining that the study design and results were insufficient to substantiate the claims being made. The company challenged the ruling in court, but the court deferred to the FTC's expertise in reviewing the sufficiency of the evidence.[8]

AGG Observations

- Companies should be mindful of their obligation not to mislead consumers. Even if a cosmetic product, for example, makes no drug claims, the advertising materials could still mislead consumers. The FTC has copy tested a variety of claims and language to determine how consumers really interpret certain statements. For example, the FTC has shown consumers advertisements making various health claims about products to evaluate what conclusions consumers draw about the health benefits of those products.[9]
- We recommend keeping product data on file to support any claims made in advertising materials, whether or not the products require pre-market submission to FDA. FDA has jurisdiction over product labeling, but the FTC may still review product labeling when it is used promotionally on a website, for example.
- Critically examine the data on file to support health claims to ensure that the data meets the competent and reliable standard. The data must be based on the expertise of professionals and conducted objectively using generally accepted procedures. Anecdotal evidence, such as testimonials, and newspaper or magazine articles are not competent and reliable scientific evidence.
- We sit on a number of promotional review committees for clients. It is important to review product advertisements and claims, keeping in mind the requirements of both FDA and the FTC.

6 FDA has requested comments on the use of the term "natural" in food labeling, so FDA may update its position. See http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last accessed 10/29/2016).
7 See https://www.ftc.gov/news-events/press-releases/2016/04/four-companies-agree-stop-falsely-promoting-their-personal-care (last accessed 10/29/2016).
8 https://www.ftc.gov/news-events/blogs/business-blog/2015/02/pom-v-ftc-dozen-quotable-quotes-dc-circuit-opinion (last accessed 10/29/2016).
9 See https://www.ftc.gov/sites/default/files/documents/reports/generic-copy-test-food-health-claims-advertising/netfood.pdf (last accessed 10/29/2016).

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