

The Federal Trade Commission (FTC) recently issued <u>Health Products Compliance Guidance</u> (the Health Guides).

The Health Guides replace prior FTC guidance issued in 1998 that largely focused on dietary supplements. The new guidance addresses advertising practices for a broader range of products, namely "any health-related product," including foods, over-the-counter drugs, homeopathic products, devices, health equipment, diagnostic tests, and health-related apps.

Key updates include:

- Revised guidance on the "clear and conspicuous" standard, including information regarding visual and audio disclosures, notice that hyperlink disclosures are inadequate (a departure from the FTC's 2013 dot.com guidance revision, which states that hyperlinks *may* be inadequate).
- Stricter definition of "competent and reliable scientific evidence," emphasizing the <u>FTC expectation</u> that advertisers will support their health-related claims with high-quality, randomized, and controlled human clinical trials. However, some existing case law calls into question this restrictive interpretation of "competent and reliable scientific findings." *See United States v. Bayer Corp.*, No. CV 07-01(JLL), 2015 WL 5822595, at *15 (D.N.J. Sept. 24, 2015).
- Updated guidance regarding key components of high-quality research and testing methodology, such as control groups, randomization, and double blinding, as well as the requirement that results be statistically significant and clinically meaningful to consumers. The FTC also warns against "p-hacking," which involves relying on an analysis of a small subset of data after failing to find a treatment effect in the population as a whole.
- Incorporation of revisions to previous FTC guidance materials, such as an enforcement policy statement on homeopathic products and direction on endorsements and testimonials.

In short, new revisions constitute a meaningful expansion of the FTC's guidance for advertising health-related products, expanding compliance to all health-related claims and emphasizing the importance of supporting these claims with competent and reliable scientific evidence. Marketers of health-related products would be well advised to review and understand the new Health Guides.

Authors



Jason S. Howell

Partner

JHowell@perkinscoie.com 206.359.3134



Jared H. Bryant

Practice Attorney

JBryant@perkinscoie.com 206.359.3664



Tim Carter

Associate TCarter@perkinscoie.com 650.838.4786



Nathan W. Kosnoff

Discovery Attorney NKosnoff@perkinscoie.com 206.359.6673

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