



United States of America
FEDERAL TRADE COMMISSION
Washington, DC 20580

Division of Advertising Practices

July 28, 2014

NameTitle
Company
Address
Dear [Name]:

This letter is to advise you that the Federal Trade Commission's ("FTC") Division of Advertising Practices has reviewed advertising on your website for products making concussion protection claims and has concerns about whether those claims are adequately substantiated.

The Commission enforces Section 5 of the FTC Act, 15 U.S.C. § 45, which prohibits deceptive or unfair acts or practices in interstate commerce, including advertising that is false, misleading, or unsubstantiated. The Commission also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which makes it unlawful to disseminate a false advertisement that is likely to induce the purchase of food, drugs, or devices. Products such as mouth guards that claim to prevent or reduce the risk of concussions are "devices" within the meaning of Section 12.

Commission law is clear that making an objective claim for a product without a reasonable basis is deceptive,¹ and that competent and reliable scientific evidence is generally needed to substantiate health and safety claims.² Moreover, retailers, as well as a product's manufacturer, can be liable for violating the FTC Act by disseminating false or unsubstantiated claims.³

In the course of reviewing your website, the FTC staff identified advertising that it believes represents, expressly or by implication, that the product in question prevents or reduces

¹ FTC Policy Statement Regarding Advertising Substantiation, appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).

² *E.g.*, *POM Wonderful, LLC*, No. 9344, 2013 FTC LEXIS 6, *146 (F.T.C. Jan. 10, 2013), *appeal docketed*, No. 13-1060 (D.C. Cir. Mar. 8, 2013) (finding "insufficient competent and reliable scientific evidence" to substantiate claims that the challenged products treat specified diseases, and that clinical studies prove they do so); *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 299 (D. Mass. 2008) ("For health-related efficacy and safety claims, the FTC has commonly insisted on 'competent and reliable scientific evidence.'" (citations omitted), *aff'd*, 624 F.3d 1 (1st Cir. 2010).

³ *Porter & Dietsch, Inc.*, 90 F.T.C. 770 (1977).

the risk of concussions. For example, the [name of product] is said to [quotation from website page re concussion protection]. See [link to website page] (last accessed July 28, 2014).

Given this claim, you should be aware of a 2012 FTC law enforcement order resolving allegations that Brain-Pad, Inc. and Joseph Manzo (together, “Brain-Pad”) violated Sections 5 and 12 of the FTC Act by making concussion protection claims for their Brain-Pad-branded line of mouthguards. In particular, the order settled charges that Brain-Pad made false and unproven claims that its mouthguards could reduce the risk of concussions. The order prohibits the respondents from making the allegedly deceptive claims challenged in the FTC’s complaint, as well as similar claims, unless they have competent and reliable scientific evidence to support the claims. The attached complaint and order describe in detail the marketing claims at issue in that case, and the order provisions required to ensure future compliance with the FTC Act.

The above-referenced claim for the [product] is merely illustrative, and is not intended to be all-inclusive. We recommend that after reviewing the attached complaint and order, you review your website to ensure that you are not disseminating concussion protection claims for which competent and reliable scientific evidence does not exist. In this regard, you might want to contact the manufacturers of products for which concussion protection claims appear on your website and inquire about the substantiation for those claims.⁴

We plan to revisit the [company name] website after 90 days. By sending this letter, we do not waive the FTC’s right to take law enforcement action and seek appropriate injunctive and monetary remedies against [company name], based on past or future violations.

Thank you for your attention to this matter. Please direct any inquiries concerning this letter to [FTC contact] at [email address] or at [telephone number].

Very truly yours,

Mary K. Engle
Associate Director for Advertising Practices

Enclosures

⁴ As you may know, Commission staff has sent warning letters to a number of manufacturers of sporting goods equipment who were making concussion protection claims for their products. See <http://www.ftc.gov/news-events/press-releases/2012/11/ftc-approves-final-order-settling-charges-against-marketer-brain> (Nov. 19, 2012).