



United States of America
FEDERAL TRADE COMMISSION
Washington, DC 20580

Division of Advertising Practices

November 7, 2012

Name
Title
Company
Address

Dear [Name]:

This letter is to advise you that the Division of Advertising Practices of the Federal Trade Commission (“FTC”) has reviewed product packaging and advertising, including advertising on the website [company’s website address], for the Product X mouthguard.

FTC staff has identified an express claim on product packaging and in advertising for the mouthguard representing the efficacy and health benefits of the product. Your marketing materials have stated that the Product X mouthguard “[advertising claim].”

Given the claim you have made, you should be aware of a recent FTC law enforcement consent order that resolved allegations that Brain-Pad, Inc. and Joseph Manzo (together, “Brain-Pad”) violated Sections 5 and 12 of the FTC Act by making similar claims in connection with their Brain-Pad-branded line of mouthguards. In particular, the consent order settled charges that Brain-Pad made false and unproven claims that its mouthguards could reduce the risk of concussions and, even more specifically, could reduce the risk of concussions from lower jaw impacts. The consent order prohibits the company from making the allegedly deceptive claims challenged in the FTC’s complaint as well as similar claims unless it has competent and reliable scientific evidence to support the claims. Attached are copies of the FTC complaint and consent order. The attached complaint and consent order describe in more detail the marketing claims at issue in the Brain-Pad matter, and the order provisions required to ensure future compliance with the FTC Act.

We strongly recommend that after reviewing the attached complaint and consent order, you review your company’s advertising, product packaging and labeling, and other promotional materials, to ensure that you are not making performance or health benefit claims for the Product X mouthguard without competent and reliable scientific evidence to support such claims. The above claim from your product’s advertising and marketing materials is merely illustrative, and is not intended to be all-inclusive. It is your responsibility to ensure that promotional materials for your products, including all product packaging and labeling, are in compliance with the FTC Act – in other words, that the performance and health-related claims for your products are substantiated. For example, you must have reliable scientific studies demonstrating that the Product X mouthguard reduces the risk of concussions to support the claim that has appeared on

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your packages and website. Likewise, you must have reliable scientific studies demonstrating that the Product X mouthguard reduces the impact to the lower jaw if your claim is limited to that benefit.

I also urge you to visit the FTC's website at <http://business.ftc.gov/advertising-and-marketing/health-claims>, which provides relevant FTC guidance for businesses.

Please send an email to [FTC contact] by [date], describing any actions that you have taken or intend to take in response to this letter to ensure your company's compliance with the FTC Act. Please be advised that if you make claims about the performance or health benefits without adequate evidence to support those claims, the FTC may take action to enforce and seek redress for any violations of the FTC Act as the public interest may require.

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

Enclosure