

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, DC 20580



Division of Advertising Practices

Mary K. Engle
Associate Director

July 9, 2019

Michael R. Gordon, Esq.
Managing Partner
GordonLaw LLP
51 Bedford Road, Suite 10
Katonah, New York 10536

Re: X2 Biosystems, Inc., FTC Matter No. 182-3097

Dear Mr. Gordon:

As you know, staff of the Federal Trade Commission's Division of Advertising Practices conducted an investigation into the advertising of the X-Patch and X-Patch Pro impact sensors by your client, X2 Biosystems, Inc., for possible violations of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52. The sensors were marketed as being able to: 1) measure the linear and rotational impacts to the head with accuracy, sensitivity, and reproducibility; and 2) accurately determine concussion risks and thereby reduce the incidence and risks of head impact injuries.

Section 5 of the FTC Act requires that advertising claims be truthful and nonmisleading, and Section 12 prohibits false advertisements for foods, drugs, devices, services, or cosmetics. Generally, health benefit claims in advertising are deceptive if the advertiser does not possess competent and reliable scientific evidence substantiating the claims prior to their dissemination. *See, e.g., FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 298-300 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010). We were concerned that the claims for your impact sensors were not adequately substantiated.

Upon careful review of the matter, including non-public information submitted to the FTC, we have determined not to recommend enforcement action at this time. In reaching this conclusion, we considered a number of factors, including that the company had modified its advertising and marketing materials, was no longer selling the X-Patch, and had never sold the X-Patch Pro.

This action is not to be construed as a determination that a violation of law did not occur, just as the pendency of an investigation should not be construed as a determination that a

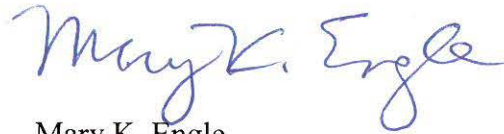
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violation has occurred. The Commission reserves the right to take such further action as the public interest may require.

Very truly yours,



Mary K. Engle
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