



United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of Advertising Practices

Mary K. Engle
Associate Director

September 17, 2018

James T. Shearin, Esq.
Pullman & Comley LLC
850 Main St.
P.O. Box 7006
Bridgeport, CT 06601-7006

Re: Cirrus Healthcare Products, L.L.C.; FTC Matter No. 1823053

Dear Mr. Shearin:

As you know, the staff of the Federal Trade Commission's Division of Advertising Practices has conducted an investigation into the advertising practices of your client, Cirrus Healthcare Products, L.L.C., for possible violations of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45, 52, in connection with efficacy claims made about the company's MigraineX earplug product. CHP marketed the device as a means to relieve migraine intensity and duration, among other things.

Section 5 of the FTC Act requires that advertising claims be truthful and non-misleading, 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 Marketing 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 CHP's migraine-related claims for its device were not adequately substantiated.

Upon careful review of this matter, including confidential information CHP provided during our investigation, we have determined not to recommend enforcement action at this time. In coming to this conclusion, we considered a number of factors, including the limited number of earplugs sold and corrective action taken by CHP, such as CHP's removal of the product and advertising claims from the marketplace. Thus, it appears that no further action is warranted at this time and the investigation is closed.

This action is not 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 further action as the public interest may warrant.

Very truly yours,

A handwritten signature in blue ink that reads "Mary K. Engle". The signature is written in a cursive style with a large, looped initial "M".

Mary K. Engle

Associate Director for Advertising Practices