



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

Office of the Secretary

August 21, 2014

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Re: *In the Matter of i-Health, Inc. and Martek Biosciences Corp.*
FTC File No. 122-3067, Docket No. C-4486

Dear Mr. Gordon:

Thank you for your comment on behalf of the Organic and Natural Health Association (ONHA) regarding the above-referenced matter. Your letter was placed on the public record pursuant to Section 2.34 of the Commission's Rules of Practice, 16 C.F.R. § 2.34, and was given serious consideration by the Commission.

In your comment, you request that the Commission withdraw the proposed complaint and consent order on the ground that an enforcement action is not in the public interest. You argue that proposed respondents had a reasonable basis for advertising that BrainStrong Adult improves memory and is clinically proven to do so.¹ Specifically, you argue that an improvement in episodic memory is an improvement in memory generally and that this claim was substantiated by the authors' stated conclusions in the *Memory Improvement with Docosahexaenoic Acid (DHA) Study* ("MIDAS Study").² You further argue that prohibiting the dissemination of advertising claims that purportedly track experts' conclusions in a published, peer-reviewed report of a randomized, double-blind, placebo-controlled study runs afoul of advertisers' First Amendment right to truthful and non-misleading commercial speech and Fifth Amendment right to due process.

When interpreting advertising claims, "the Commission may rely on its own reasoned analysis of the advertisements themselves, without resorting to surveys or consumer testimony," and its conclusions are "due special deference owing to the nature of the inquiry and the Commission's expertise in evaluating deception." *Thompson Med. Co. v. FTC*, 791 F.2d 189,

¹ Your comment also asserts, without supporting argument, that the respondents had a reasonable basis for the claim that BrainStrong Adult prevents cognitive decline.

² Karin Yurko-Mauro et al., *Beneficial Effects of Docosahexaenoic Acid on Cognition in Age-Related Cognitive Decline*, 6 *Alzheimer's & Dementia* 456 (2010).

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197 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Likewise, the Commission has “special expertise in determining what sort of substantiation is necessary to assure that advertising is not deceptive.” *Id.* at 196. As indicated in the individual Commissioners’ statements in this matter, the Commission considered the issues underlying your concerns about claim interpretation and substantiation in determining whether to issue the proposed complaint and consent order. A majority of the Commission had reason to believe that the advertising claims that appeared on television, the internet, and on product packaging were false or unsubstantiated and, hence, actually misleading. Deceptive commercial speech is entitled to no First Amendment protection. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of NY*, 447 U.S. 557, 566 (1980).

In addition, issuing the proposed complaint and consent order in this matter does not implicate the respondents’ Fifth Amendment rights because they had sufficient notice of the Commission’s substantiation standard from Commission policy statements and decisions, as well as staff guidance and federal court decisions. *See FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987)); *FTC Enforcement Policy Statement on Food Advertising* (1994); *FTC, Dietary Supplements: An Advertising Guide for Industry (“Dietary Supplements Guide”)* (Apr. 2001); *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59; *Removatron Int’l Corp.*, 111 F.T.C. 206, 297-99 (1988). These materials make clear that the determination of adequate substantiation is a fact-specific inquiry, based on expert opinion. In making this determination, the Commission is obliged to assess the quality and reliability of the scientific evidence underlying challenged advertising claims. When that evidence is a study, the Commission must determine whether the objective results “translate into a meaningful benefit for consumers.” *Dietary Supplements Guide* at 12 (“Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.”). Even after peer review, published articles may have flaws due to the reviewers’ fallibility, or the results may not match the authors’ stated conclusions. *See id.* (“[A]dvertisers should not rely simply on the fact that research is published as proof of the efficacy of a supplement....[P]ublication does not necessarily mean that such research is conclusive evidence of a substance’s effect.”).

After carefully considering your comment, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission’s website at <http://www.ftc.gov>.

It helps the Commission’s analysis to hear from a variety of sources in its work, and we thank you again for your letter.

By direction of the Commission, Commissioner Ohlhausen dissenting and Commissioner McSweeney not participating.

Donald S. Clark
Secretary