



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

Office of the Secretary

August 21, 2014

Caleb Laieski
Commonwealth of Virginia

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

Dear Mr. Laieski:

Thank you for your comment 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 state that the proposed consent order in this matter requires the respondents to have two randomized controlled trials (RCTs) to support the challenged advertising claims going forward. In fact, the proposed order requires adequate "human clinical testing" to support future claims about improving memory or preventing cognitive decline in adults, and does not specify a required number of human clinical tests to substantiate these claims. For other claims about the health benefits, performance, safety, or efficacy of any product covered by the order, respondents must possess competent and reliable scientific evidence, which, depending on the claim, will not necessarily have to consist of human clinical testing.

Your comment further argues that the proposed consent order broadens the scope of when RCTs are required to substantiate claims about dietary supplements. The proposed order, however, follows the principle articulated in numerous Commission policy statements and decisions, as well as staff guidance and federal court decisions, that the proper level of substantiation is a factual determination rooted in the nature of the product, the claim, and the opinion of relevant experts. *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* (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). Here, respondents' advertisements claimed that BrainStrong Adult improves memory and is clinically proven to do so. Experts in cognitive science generally would expect such clinical proof to consist of human clinical testing in the form of one or more randomized, double-blind, placebo-controlled trials. Even if the respondents had not claimed to have clinical proof of the memory benefit, cognitive experts would expect human clinical testing that

Caleb Laieski
August 21, 2014
Page 2

substantiates the claim that the supplement is efficacious for improved memory. The same is true of the claim that BrainStrong Adult prevents cognitive decline in adults.

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