UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Secretary

Commission Letter Addressing Public Comments
In the Matter of Carrot Neurotechnology, Inc, Adam Goldberg, and Aaron Seitz
FTC File No. 142-3132, Docket No. C-4567

Thank you for your comment regarding the proposed complaint and consent agreement in the above-referenced matter. The Commission has placed your comment on the public record pursuant to Section 2.34(b)(6)(ii) of the Commission's Rules of Practice, 16 C.F.R. § 2.34(b)(6)(ii), and has given it serious consideration.

We appreciate the opportunity to consider the issues you and other commenters raised. After the proposed complaint and consent order were placed on the public record, one of the respondents, Aaron Seitz, publicized his characterizations of the matter's nature and scope. The Commission carefully considered the issues raised by Dr. Seitz prior to accepting the complaint and order for public comment. Although the Commission's actions in this matter partially rely on non-public information gathered in the underlying investigation, we hope our additional explanation will be both clarifying and useful.

We note initially that the proposed complaint in this matter does not challenge the validity of perceptual learning in general or the evidentiary standards for conducting basic research in this field. Rather, the complaint allegations are limited to the specific advertising claims that the respondents made for Ultimeyes. The challenged advertising for Ultimeyes represented, among other things, that: it was "scientifically shown to improve vision" and "Will Improve Your Vision By 31%"; "100% of ULTIMEYES® users have experienced improvements in vision"; Ultimeyes would "Reverse the effects of aging eyes"; and it "delivers affordable, safe, and comprehensive vision improvement for sports, reading, driving, and relieving the need for traditional visual aids used for age related vision eye conditions such as presbyopia and loss of contrast sensitivity." The complaint alleges the respondents did not have substantiation for these specific and unqualified vision improvement claims.

Some commenters expressed concern about the Commission's authority to interpret advertising claims and evaluate claim substantiation for Ultimeyes. The Commission has long-standing authority and experience to regulate advertising claims for devices under Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52. When interpreting advertising claims, the Commission's 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, 197 (D.C. Cir. 1986). 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 set forth in federal and administrative court decisions, and as articulated in numerous Commission policy statements and staff guidance materials, the proper level of substantiation is a factual and context-dependent determination grounded 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)); *Thompson Med. Co.*, 104 F.T.C. at 821-22 n.59; *Removatron Int'l Corp.*, 111 F.T.C. 206, 297-99 (1988). When determining the proper level of substantiation for health-related claims, Commission staff regularly consults with experts in the relevant health and regulatory spheres (e.g., experts in the fields of neurology, vision, and the design of clinical trials), including experts at other government agencies such as the Food & Drug Administration and the National Institutes of Health.

Some commenters, including colleagues of Dr. Seitz and other scientists, expressed concern about Part I of the order, which requires the respondents to have appropriately rigorous clinical testing as substantiation before they can make the advertising claims challenged in the complaint. Commenters noted that Dr. Seitz's articles were published in peer-reviewed journals, that articles in the general scientific literature support the idea that perceptual learning may improve vision, and that it would be difficult to blind or control a study of a video game. Some of these same commenters expressed concern that the standard set forth in the order could chill future research and pointed out that there is no absolute proof in science.

We note that, in evaluating substantiation for advertising claims, the Commission assesses the quality and reliability of the scientific evidence underlying the claim. In this regard, peer review, while valuable and often indicative of a well-designed and executed study, is not a guarantor of high quality. During an investigation, the Commission may obtain additional information, not available to the peer reviewers, that is relevant to an assessment of the reliability and implications of the peer-reviewed study. For instance, this additional information may identify study design flaws, misreporting of the underlying data, or improper data analysis. Moreover, results from a peer-reviewed study may support some claims, but not the specific advertising claims the Commission has challenged.

The Commission believes clinical testing with proper blinding and controls is reasonable and appropriate substantiation for the specific and unqualified vision improvement claims at issue. Such measures will help ensure that the advertised vision improvement is caused by Ultimeyes, and not by alternative causes, biases, or other effects engendered by subject or investigator expectation or engagement. The Commission recognizes, as pointed out by some commenters, that subjects will know that they are playing a video game, but blinding in this context means the subjects will not know if their game contains the intervention being tested (and, thus, that they are in the test group). Additionally, subjects could be blinded to the study hypothesis. On the investigator side, blinding means using measures to avoid biases in collecting and analyzing data and influencing, through interaction or otherwise, subject expectations. Thus, before and after results measured and analyzed entirely by computer could be de facto double blinded. What constitutes appropriate blinding and controls, therefore, may differ depending on the nature of the intervention and other circumstances. For that reason, Part I does not prescribe a specific set of blinding procedures or require a particular task as an active control. We also note that the general scientific literature on perceptual learning, as well as Dr. Seitz, have advocated for the use of such measures as feasible and necessary. *See, e.g.*, C.S. Green & D. Bavelier, *Learning, Attentional Control, and Action Video Games*, 22 Current Biology R197-R206 (2012) ("The best way to address this issue is the presence of a well thought-out active control group,

whereby all training appears equally active to participants . . . as well as keeping engagement roughly matched across groups," and noting two state of the art examples: the control group can play a less challenging version of the same game or a different video game)); J. Deveau & A.R. Seitz, *Applying Perceptual Learning to Achieve Practical Changes in Vision*, Frontiers in Psychol. (Oct. 2014) ("[f]uture studies with a double blind active control group are essential in determining the effectiveness of perceptual learning based vision training.").

A few commenters indicated that they used Ultimeyes and believed it improved their vision. Although the Commission appreciates hearing about consumers' individual experiences, anecdotal user evidence is not reliable support for a claim that a product will cause the same effect in the general population.

Some commenters raised concerns about the equitable monetary remedy. Some believed it to be excessive, while others noted that they believed a large "fine" imposed on a researcher could discourage other researchers and chill innovation. The Commission does not have the authority to impose a fine for an initial violation of the FTC Act. However, as is the case here, it often seeks equitable monetary relief based on consumer injury or ill-gotten gains attributed to the law violation. Individuals are often jointly responsible with a corporation for both conduct and monetary relief, particularly if the corporation is essentially the alter ego of the individuals. *See, e.g.*, *FTC v. Affordable Media*, 179 F.3d 1228, 1234 (9th Cir. 1999); *Southwest Sunsites, Inc.*, 105 F.T.C. 7, 370-73 (1980), *aff'd sub nom., Southwest Sunsites, Inc. v. FTC*, 785 F.2d 1431 (9th Cir. 1986). The Commission also considers ability to pay, if raised by a respondent, in accepting a settlement amount. The complaint in this case alleges that sales of Ultimeyes – the consumer injury – exceeded $350,000. Based on all the information available in this case, the respondents, including Dr. Seitz, and counsel for the Commission settled for equitable monetary relief of $150,000, which the Commission believes is an appropriate amount.

Several commenters believed that other targets would be more appropriate for Commission action. The Commission appreciates commenters' referrals of other advertising they believe is deceptive; however, possible wrongdoing by others does not obviate the need for the Commission to address respondents' alleged law violations.

After carefully considering your comment, along with others received in this matter and the investigative record, the Commission has determined that the proposed relief set forth in the consent agreement is appropriate and necessary to remedy the violations alleged in the proposed complaint, and it is in the public interest to issue the Decision and Order in final form without modification. A copy of the final Decision and Order, along with other relevant materials, is available from the Commission's website at http://www.ftc.gov.

Thank you again for your comment. Hearing from a variety of sources aids the Commission in its analysis, and we appreciate your interest in the matter.

By direction of the Commission.

Donald S. Clark
Secretary