ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT In the Matter of Carrot Neurotechnology, Inc., File No. 142 3132

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order as to Carrot Neurotechnology, Inc., Adam Goldberg, and Aaron Seitz (hereafter "respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the respondents' advertising for the Ultimeyes software application. The Commission's complaint alleges that the respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a), 52, by representing, either falsely or without adequate substantiation, that Ultimeyes substantially improves users' vision, including that it: improves the vision of users, including people of all ages, genders, and visual abilities; improves vision with real world benefits, including benefits across a broad range of activities ranging from athletics to more routine lifestyle activities, such as reading, watching TV, and driving; improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users' ability to read in dim light, and diminishing the need for glasses or other visual aids. The complaint also alleges that the respondents violated Sections 5(a) and 12 by making the false or misleading representation that scientific testing proves that Ultimeyes improves vision in the above ways.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The order applies to marketing claims for any Covered Product or Service, defined as any Device within the meaning of Sections 12 and 15 of the FTC Act, 15 U.S.C. §§ 52, 55, or any program or service that is: (1) intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (2) intended to affect the structure or any function of the body of man or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes. As additional fencing-in relief, the order requires the respondents to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that it conducts or sponsors on any Covered Product or Service.

Part I prohibits any representation that a Covered Product or Service improves users' vision, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must consist of human clinical testing of the Covered Product or Service that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall (1) be randomized, double-blind, and adequately controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, the respondents must maintain all underlying or supporting data that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part II prohibits any representation about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or Service, unless it is nonmisleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons; and that are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of human clinical tests or studies, the respondents must maintain all underlying or supporting data and documents that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part III, triggered when the human clinical testing requirement in Parts I or II applies, requires the respondents to secure and preserve all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test that is published in a peer-reviewed journal and that was not conducted, controlled, or sponsored by any respondent or by any supplier of the respondents. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part IV prohibits the respondents from misrepresenting, including through the use of a name, endorsement, depiction, or illustration, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or that any benefits of a product, program, or service are scientifically proven.

Part V requires the respondents to disclose, when triggered by certain representations as to scientific support or endorsements in connection with the advertisement or sale of any product, program, or service, any material connections to any person that has conducted, authored, or participated in any test, study, or research of the product, program, or service; and all material connections between a person providing an endorsement and respondents or any other person manufacturing, labeling,

advertising, promoting, offering for sale, selling, or distributing such product, program, or service.

Part VI provides the respondents will pay an equitable monetary payment of \$150,000 and contains other provisions related to the payment.

Part VII requires the respondents to provide sufficient customer information to administer redress.

Part VIII contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III, as well as order acknowledgments covered by Part IX.

Parts IX through XI require the respondents to deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the order's subject matter, notify the Commission of changes in corporate structure that might affect compliance obligations, and file compliance reports with the Commission.

Part XII provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.