Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Creative Health Institute, Inc. and Kyl L. Smith
File No. 012 3248

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Creative Health Institute, Inc., and Kyl L. Smith, individually and as an officer of the corporation.

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

This matter involves practices relating to the advertising and promotion of Focus Factor, a dietary supplement containing, among other things, vitamins, minerals, botanicals, and amino acids. Marketing materials for Focus Factor claimed that the product enhanced brain function and improved the focus, memory, mood, concentration, and energy of children, adults, and seniors.

According to the FTC complaint, the respondents failed to have substantiation for their claims that Focus Factor: (a) improves the focus, memory, and concentration of healthy adults; (b) alleviates stress and combats the fatigue, irritability and mood swings that healthy adults experience; (c) makes children and teenagers feel more alert, focused, and mentally sharp; (d) improves students' ability to concentrate and their academic performance; (e) improves senior citizens' memory, mental clarity, and energy; (f) improves adults' ability to absorb information in books and to recall facts, figures and names; and (g) works in as little as one to ten days.

The complaint also alleges that the respondents failed to disclose that certain of the endorsers who appeared in advertising for Focus Factor had material connections with the product.

The proposed consent order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that Focus Factor or any substantially similar product (defined as any ingestable dietary supplement containing one or more specified ingredients): (a) improves the focus, memory, and concentration of healthy adults; (b) alleviates stress, fatigue, irritability and mood swings in healthy adults; (c) makes children and teenagers feel more alert, focused, and mentally sharp; (d) improves students' ability to concentrate and their academic performance; (e) improves senior citizens' memory, mental clarity, and energy; (f) improves adults' ability to absorb information in books and to recall facts, figures and names; or (g) works in as little as one to ten days, unless the claims are substantiated by competent and reliable scientific evidence.

Part II requires that the respondents possess competent and reliable scientific evidence to support any future claims about the benefits, performance, or efficacy of any food, drug, or dietary

supplement for: (a) the brain or any mental functions or processes (including, but not limited to cognitive function, memory, focus, learning or concentration); (b) stress, anxiety, energy, mood or behavior; (c) academic or business performance; (d) longevity, age-related memory impairment or dementia; or (e) the treatment, cure, mitigation, alleviation of the symptoms, prevention or reduction in the risk of any mental, brain, or central nervous system disease or disorder.

Part III requires disclosure of any material connection that exists between an endorser and the respondents or any other person or entity involved in marketing or selling the food, drug or dietary supplement that is the subject of the endorsement.

Part IV permits any representation for any product that is permitted in labeling for such product by the FDA pursuant to the Nutrition Labeling and Education Act of 1990, and any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the FDA or under any new drug application approved by the FDA.

Part V states that nothing in the order shall be constituted as a waiver of the respondents' rights to engage in speech protected by the First Amendment to the Constitution.

Part VI provides for the payment of $60,000 to the Commission.

Part VII requires the respondents to retain certain records for five (5) years after the last date of dissemination of any representation covered by the order: (1) all advertisements and promotional materials containing the representation; (2) all materials relied upon in disseminating the representation; and (3) all evidence in respondents' possession or control that contradicts, qualifies, or calls into question the representation or the basis for the representation.

Part VIII requires the respondents for ten (10) years to provide copies of the order to personnel having responsibilities relating to the subject matter of the order, and to obtain signed copies acknowledging receipt of the order.

Part IX requires that the Commission be notified of changes in corporate structure that might affect compliance obligations arising under the order. Part X requires that the individual respondent notify the Commission for five (5) years of any changes in employment that might affect his compliance obligations arising under the order.

Part XI requires the respondents to file compliance reports with the Commission.

Part XII provides that the order will terminate after twenty (20) years under certain circumstances.

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