UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman Mozelle W. Thompson Orson Swindle Thomas B. Leary Pamela Jones Harbour

In the Matter of

CREATIVE HEALTH INSTITUTE, INC.,
a corporation, and

KYL L. SMITH,
individually and as an officer of Creative Health
Institute, Inc.

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

- 1. Respondent Creative Health Institute, Inc. ("Creative Health") is a Texas corporation with its principal office or place of business at 4451 FM 2181, Suite 100-515, Corinth, Texas 76205.
- 2. Respondent Kyl L. Smith ("Smith") is an officer and sole director of respondent Creative Health. Individually or in concert with others, he formulates, directs, controls or participates in the policies, acts, or practices of Creative Health, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of Creative Health.
- 3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

- 1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- 2. Unless otherwise specified, "respondents" shall mean Creative Health Institute, Inc. and its respective successors and assigns, and officers, agents, representatives, and employees, and Kyl L. Smith, his respective agents, representatives and employees.
- 3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 4. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
- 5. "Substantially similar product" shall mean any ingestable dietary supplement containing one or more of the following ingredients: phosphatidyl serine; Dimethyl-aminoethanol (DMAE); docosahexaenoic acid (DHA); L-glutamine, L-pyroglutamic acid; pyridoxal alpha ketoglutarate, –acetyl-tyrosine, GABA, inositol, bilberry, pine bark; bacopa monnieri, Coenzyme Q-10, huperzine, choline, vinpocetine; boron; or vanadium.

IT IS ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of Focus Factor or any substantially similar product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, that:

- a. Such product improves the focus, memory, and concentration of healthy adults;
- b. Such product alleviates stress, fatigue, irritability and mood swings in healthy adults:
- c. Such product makes children and teenagers feel more alert, focused, and mentally sharp;
- d. Such product improves students' ability to concentrate and their academic performance;
- e. Such product improves senior citizens' memory, mental clarity, and energy;
- f. Such product improves adults' ability to absorb information in books and to recall facts, figures and names; or
- g. Consumers who start taking such product regularly will feel its effects in as little as one to ten days;

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any food, drug, or dietary supplement, as "food" and "drug," are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the benefits, performance or efficacy of such product 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;

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any food, drug, or dietary supplement, as "food" and "drug," are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall disclose, clearly and prominently, a material connection, when one exists, between a person providing an endorsement for any product, and any respondent, or any individual or entity labeling, advertising, promoting, offering for sale, selling, or distributing such product. For purposes of this Part, "material connection" shall mean any relationship that might materially affect the weight or credibility of the endorsement.

IV.

Nothing in this order shall prohibit respondents from making any representation:

- A. For any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.
- B. For any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

Nothing in this order shall be constituted as a waiver of respondents' right to engage in speech protected by the First Amendment to the Constitution of the United States.

IT IS FURTHER ORDERED that respondents shall pay to the Federal Trade Commission the sum of sixty thousand dollars (\$60,000). This payment shall be made in the following manner:

- A. The payment shall be made by wire transfer or certified or cashier's check made payable to the Federal Trade Commission, the payment to be made no later than fifteen (15) days after the date that this order becomes final.
- B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable.
- C. The funds paid by respondents, together with any accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of Focus Factor in connection with the acts or practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty or punitive assessment.
- D. Respondents relinquish all dominion, control and title to the funds paid, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of either respondent, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

VII.

IT IS FURTHER ORDERED that respondents Creative Health Institute, Inc. and Kyl L. Smith, their successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation including videotape recordings of all such broadcast advertisements;

- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VIII.

IT IS FURTHER ORDERED that respondent Creative Health Institute, Inc. and its successors and assigns, and respondent Kyl L. Smith, for a period of ten (10) years after the date of issuance of this order, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IX.

IT IS FURTHER ORDERED that respondent Creative Health Institute, Inc., and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any proposed change in its corporate structure that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent Creative Health Institute, Inc. learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondent Kyl L. Smith, for a period of five (5) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his

current business or employment, or of his affiliation with any new business or employment that may affect his compliance obligations arising out of this Order. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XI.

IT IS FURTHER ORDERED that respondent Creative Health Institute, Inc. and its successors and assigns, and respondent Kyl L. Smith shall, within sixty (60) days from the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

XII.

This order will terminate on April 26, 2024, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; <u>provided, however</u>, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

<u>Provided further</u>, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed

and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark Secretary

SEAL

ISSUED: April 26, 2004