Analysis of Proposed Consent Order to Aid Public Comment In the Matter of Vital Basics, Inc., Robert B. Graham, and Michael B. Shane File No. 012 3248

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Vital Basics, Inc., and Robert B. Graham and Michael B. Shane, individually and as officers 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 two products: Focus Factor and V-Factor Natural Pack. Focus Factor is 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. V-Factor Natural Pack is a dietary supplement containing, among other things, yohimbine and L-argenine that was marketed as a men's sexual performance enhancer.

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 further alleges that the respondents failed to have substantiation for their claims that V-Factor Natural Pack is safe for virtually all men, and falsely represented that a clinical study of the V-Factor Natural Pack conducted by Dr. Carlon Colker proves that V-Factor is safe and is effective at improving sexual response and function.

Finally, the complaint alleges that the respondents: (1) failed to disclose that certain of the consumer and expert endorsers who appeared in advertising for Focus Factor had material connections with the companies and individuals marketing the product, and that other consumer endorsements were solicited by the promise of a free 6-month supply of Focus Factor to those individuals whose testimonials were used in the company's advertising; and (2) misrepresented that certain radio infomercials were independent radio programs, not paid commercial advertising.

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 representations 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 safety, performance, benefits, 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), stress, anxiety, energy, mood or behavior, academic or business performance, longevity, age-related memory impairment or dementia; (b) sexual response, function, enhancement, or performance; or (c) the treatment, cure, mitigation, or prevention, of any disorder. Although the order does not prohibit the trade name "Focus Factor," it does require the respondents to have competent and reliable scientific evidence to substantiate any covered claims conveyed directly or by implication through the use of the product name.

Part III requires that the respondents possess competent and reliable scientific evidence to support any future claims that V-Factor Natural Pack or any product containing yohimbine is safe.

Part IV prohibits any misrepresentation of the existence, contents, validity, results, conclusions, or interpretations of any test or study, in connection with the marketing of sale of any product or program.

Part V 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 product or program that is the subject of the endorsement.

Part VI prohibits the creation or dissemination of any advertisement that misrepresents that it is not a paid advertisement, and requires that specific disclosures be included in any video or radio advertisement that is at least fifteen minutes in length.

Part VII 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.

Part VIII provides for the payment of \$1 million to the Commission.

Part IX 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 X 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 XI requires that the Commission be notified of changes in corporate structure that might affect compliance obligations arising under the order.

Part XII requires that the individual respondents notify the Commission for five (5) years of any changes in employment that might affect their compliance obligations arising under the order.

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

Part XIV 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.