

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.

By direction of the Commission.

Donald S. Clark,

Secretary.

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FEDERAL TRADE COMMISSION

[File No. 012 3248]

Vital Basics, Inc., et al.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of Federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before April 16, 2004.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: consentagreement@ftc.gov, as prescribed in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Heather Hipsley or Shira Modell, FTC, Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-3285 or 326-3116.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment

describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 17, 2004), on the World Wide Web, at "<http://www.ftc.gov/os/2004/03/index.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room 130-H 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled "confidential." Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following e-mail box: consentagreement@ftc.gov. Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii).

Analysis of Proposed Consent Order To Aid Public Comment

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-arginine 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 ingestible 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.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

The Secretary of Health and Human Services (HHS) has determined that the establishment of the National Science Advisory Board for Biosecurity (Committee) is necessary and in the public interest in connection with the duties of the Administration and that such duties can best be performed through the advice and counsel of such a group.

This Committee shall advise the Secretary of Health and Human Services; the Director, National Institutes of Health; and the heads of all federal departments and agencies that conduct or support life sciences research. The Committee will advise on and recommend specific strategies for the efficient and effective oversight of dual use biological research, taking into consideration both national security