[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 122 3287]

HealthyLife Sciences, LLC; 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. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint 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 October 14, 2014.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/healthylifesciencesconsent online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "In the Matter of HealthyLife Sciences, LLC - Consent Agreement; File No. 122 3287" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/healthylifesciencesconsent by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Elizabeth Nach, Bureau of Consumer Protection, (202-326-2611), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing 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 September 11, 2014), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 14, 2014. Write "In the Matter of HealthyLife Sciences, LLC - Consent Agreement; File No. 122 3287" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include

any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/healthylifesciencesconsent by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "In the Matter of HealthyLife Sciences, LLC - Consent Agreement; File No. 122 3287" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600

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[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 14, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from HealthyLife Sciences, LLC ("HealthyLife Sciences").

The proposed consent order ("proposed 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 HealthyLife Science's advertising for its Healthe Trim line of weight-loss dietary supplements ("Healthe Trim"). The complaint alleges that the company violated Sections 5(a) and 12 of the Federal Trade Commission Act by making false or

unsubstantiated representations that Healthe Trim would cause rapid and substantial weight loss, including as much as 35, 130, and 165 pounds. It also claimed that users would lose weight without dieting, and that Healthe Trim would burn fat, increase metabolism, and suppress appetite. The complaint also alleges that HealthyLife Sciences violated Sections 5(a) and 12 by falsely representing that Healthe Trim is clinically proven to cause weight loss.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. For purposes of the order, "Covered Product" means any dietary supplement, food, or drug.

Part I of the proposed order bans HLS from making any of the seven "gut check" weight loss claims that the Commission has publicly advised are always false, specifically that any dietary supplement, over-the-counter drug, or patch, cream, wrap, or other product worn on the body or rubbed into the skin: 1) causes weight loss of two pounds or more a week for a month or more without dieting or exercise; 2) causes substantial weight loss no matter what or how much the user eats; 3) causes permanent weight loss; 4) blocks the absorption of fat or calories to enable users to lose substantial weight; 5) safely enables users to lose more than three pounds per week for more than four weeks; 6) causes substantial weight loss for all users; or 7) causes substantial weight loss by wearing a product on the body or rubbing it into the skin.

Part II of the proposed order prohibits HLS from making claims that any Covered Product causes weight loss, causes substantial or rapid weight loss, causes weight loss without the need to diet or make lifestyle changes, burns fat or causes fat loss, boosts metabolism, or suppresses appetite, unless it possesses and relies upon competent and reliable scientific evidence, defined as at least two adequate and well-controlled human clinical studies. The studies must have been conducted by qualified persons, and have been randomized, double-

blinded, and placebo-controlled. In addition, the company must maintain all underlying or supporting data that experts in weight-loss research generally would accept as relevant to an assessment of such testing.

Part III of the proposed order prohibits any representation about the health benefits, performance, or efficacy of any Covered Product, unless it is non-misleading 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 is defined as tests, analyses, research, or studies that have been conducted by qualified persons in an objective manner and are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of human clinical tests or studies, HLS must maintain all underlying or supporting data and documents that experts in the field generally would accept as relevant to an assessment of such testing.

Part IV of the proposed order prohibits HLS from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research in connection with the manufacturing, labeling, advertising, promotion, offering for sale, and sale or distribution of any Covered Product.

Part V provides a safe harbor for representations permitted under any tentative final or final standard promulgated by the Food and Drug Administration ("FDA"), any new drug application approved by the FDA, or FDA regulations pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997.

Triggered when the human clinical testing requirement in Part II or III applies, Part VI of the proposed order requires HLS to secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the human clinical test or study, 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 published in a peer-reviewed journal that was not conducted, controlled, or sponsored by HLS, its affiliates, or others in the manufacturing and supply chain. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Parts VII through X of the proposed order require HLS to: deliver a copy of the order to principals, officers, directors and other employees having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part XI provides that the order will terminate after twenty (20) years, with certain exceptions.

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 complaint or proposed order, or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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