In the Matter of HealthyLife Sciences, LLC

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT
File No. 122 3287

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.