

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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| In the Matter of |) | |
| |) | FILE NO. 122 3287 |
| HEALTHYLIFE SCIENCES, LLC, |) | |
| a limited liability company. |) | AGREEMENT CONTAINING |
| |) | CONSENT ORDER |
| |) | |

The Federal Trade Commission (“Commission”) has conducted an investigation of certain acts and practices of HealthyLife Sciences, LLC (“proposed respondent”). Proposed respondent is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between HealthyLife Sciences, by its duly authorized officers, and counsel for the Federal Trade Commission that:

1. Proposed respondent HealthyLife Sciences, LLC (“HealthyLife Sciences”) is a Georgia limited liability company with its

5. “Essentially Equivalent Product” shall mean a product that contains the identical ingredients, except for inactive ingredients (*e.g.*, binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (*e.g.*, orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the relevant field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

6. “Food” and “Drug” mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

7. “Reliably Reported,” for a human clinical test or study (“test”), means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

8. The term “including” in this Order shall mean “without limitation.”

9. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Dietary Supplement, over-the-counter Drug, or patch, cream, wrap, or other product worn on the body or rubbed into the skin, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of product name, endorsement, illustration, trademark, or trade name, that such product:

- A. Causes weight loss of two pounds or more a week for a month or more without dieting or exercise;
- B. Causes substantial weight loss no matter what or how much the user eats;
- C. Causes permanent weight loss;
- D. Blocks the absorption of fat or calories to enable users to lose substantial weight;
- E. Safely enables users to lose more than three pounds per week for more than four weeks;
- F. Causes substantial weight loss for all users; or
- G. Causes substantial weight loss by wearing a product on the body or rubbing it into the skin.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, other than representations banned under Part I of this Order, in any manner, expressly or by implication, including through the use of

Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study (“test”) upon which respondent relies to substantiate any claim covered by this Order, respondent shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including, but not necessarily limited to:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test’s researchers.

Provided, however, the preceding preservation requirement shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by respondent, or by any person or entity affiliated with or acting on behalf of respondent, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with respondent (“respondent’s affiliates”), (2) by the supplier or manufacturer of the product at issue, or (3) by a supplier to respondent, to respondent’s affiliates, or to the product’s manufacturer of any ingredient contained in such product.

For any test conducted, controlled, or sponsored, in whole or in part, by respondent, respondent must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to respondent’s size and complexity, the nature and scope of respondent’s activities, and the sensitivity of the personal information collected from or about the participants.

VII.

IT IS FURTHER ORDERED that respondent and its successors and assigns, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- 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 and its successors and assigns shall deliver a copy of this Order to all current and future principals, officers, directors, and other employees 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. Respondent shall deliver this Order to current personnel within thirty (30) days after 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 and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the company, that may affect compliance obligations arising under this Order, including, but not limited to, 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; o.0007 -1s,t3 0 TDi5ilny
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X.

IT IS FURTHER ORDERED that respondent and its successors and assigns, within sixty (60) days after the date of service of this Order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate reports.

XI.

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; *provided, however*, 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.

Provided, further, that if such complaint is dismissed or a federal court rules that 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.

Signed this ____ day of _____, 2014.

ASSET RECOVERY ASSOCIATES, LLC
Solely in its capacity as assignee for
HealthyLife Sciences, LLC

By: _____
CURT FRIEDBERG
Partner

By: _____
CHRISTINE L. DELORME
ELIZABETH NACH
Counsel for the Federal Trade Commission

APPROVED:

MARY K. ENGLE
Associate Director
Division of Advertising Practices

JESSICA L. RICH
Director
Bureau of Consumer Protection