122 3287

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
	)	**DOCKET NO. C-4493**
HEALTHYLIFE SCIENCES, LLC,	)	
a limited liability company.	)	

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order ("consent agreement") that includes: a statement that the agreement is for settlement purposes only and does not constitute an admission that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true; and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent HealthyLife Sciences, LLC is a Georgia limited liability company with its principal office or place of business at 8601 Dunwoody Place, Suite 418, Atlanta, Georgia 30350.

2. The Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" shall mean HealthyLife Sciences, LLC, its successors and assigns, and officers, and their agents, representatives, and employees.

2. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

3. "Covered Product" shall mean any Dietary Supplement, Food, or Drug.

4. "Dietary Supplement" means:

   a. Any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or

   b. Any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that is a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

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 product name, endorsement, illustration, trademark, or trade name, that such product:

A. Causes weight loss;

B. Cause substantial weight loss;

C. Causes rapid weight loss;

D. Causes weight loss without the need to diet, give up any foods, or make any changes in lifestyle;

E. Causes users to burn fat or lose fat;

F. Increases users' metabolism; or

G. Causes suppression of appetite;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of this Part, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the Covered Product, or of an Essentially Equivalent Product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Respondent shall have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

For purposes of this Part, "adequate and well-controlled human clinical study" means a human clinical study (1) that is randomized, double-blind, and placebo-controlled; (2) that is conducted by persons qualified by training and experience to conduct such a study; and (3) as to which, all underlying or supporting data and documents generally accepted by experts in weight loss research as relevant to an assessment of such testing as described in Part VI must be available for inspection and production to the Commission.

III.

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 covered under Parts I and II of this Order, in any manner, expressly or by implication, including through the use of product name, endorsement, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon 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 means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in Part VI must be available for inspection and production to the Commission.

IV.

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 misrepresent, in any manner, expressly or by implication:

A. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or

B. That the efficacy of such product has been clinically or scientifically proven.

V.

IT IS FURTHER ORDERED that:

A. Nothing in this Order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this Order shall prohibit respondent from making any representation for any product specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education 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; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent learns fewer than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: HealthyLife Sciences, LLC, FTC File No. 122-3287.

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 on October 22, 2034, 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.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: October 22, 2014