

withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to the proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time frame provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right he may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

6. Proposed respondent has read the draft complaint and consent order. Proposed respondent understands that he may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

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

1. Unless otherwise specified, "respondent" means John Matthew Dwyer III.
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. “Food” and “Drug” mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.
6. “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.
7. The term “including” in this Order shall mean “without limitation.”
8. 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 is permanently restrained and enjoined from manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing, or assisting others in manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing, any weight-loss product or program.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, 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 Part I of this Order, in any manner, expressly or by implication, including through the use of product name, endorsement, depiction, 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 V 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, licensee, affiliate, trade name, 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.

IV.

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.

V.

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, 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, or by any business for which respondent is the majority owner, or directly or indirectly controls, respondent or such business 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 such business's size and complexity, the nature and scope of such business's activities, and the sensitivity of the personal information collected from or about the participants.

VI.

IT IS FURTHER ORDERED that respondent shall, 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 his 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.

VII.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this Order to all current and future principals, officers, directors, and other employees having managerial

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. Delivery shall occur 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.

VIII.

IT IS FURTHER ORDERED that respondent, for a period of seven (7) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment, within 14 days of such change occurring. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent, 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 his 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.

X.

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.

By: _____
John Matthew Dwyer III, individually

By: _____
Christine L. DeLorme
Elizabeth Nach
Counsel for the Federal Trade Commission

APPROVED:

Mary K. Engle
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Jessica L. Rich
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