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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-4486**
I-HEALTH, INC.,	)	
a corporation, and	)	
	)	
MARTEK BIOSCIENCES CORP.,	)	
a corporation.	)	
	)	

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents 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 respondents with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

The respondents, their attorneys, 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 respondents have 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 comment, and having duly considered the comments filed thereafter by interested persons 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 i-Health, Inc. is a Delaware corporation with its principal office or place of business at 55 Sebethe Drive, Cromwell, Connecticut 06416.

2. Respondent Martek Biosciences Corporation was a Delaware corporation with its principal office or place of business at 6480 Dobbin Road, Columbia, Maryland 21045. On June 30, 2012, Martek Biosciences Corporation merged into its successor, DSM Nutritional Products, LLC. DSM Nutritional Products, LLC is a Delaware corporation with its principal office or place of business at 45 Waterview Boulevard, Parsippany, New Jersey 07054.

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

ORDER

DEFINITIONS

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

1. Unless otherwise specified, "Respondents" means i-Health, Inc. and Martek Biosciences Corporation, and their successors and assigns.

2. DSM Nutritional Products, LLC is a successor of Martek Biosciences Corporation.

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

4. "Covered Product" means any dietary supplement, food, or drug promoted to prevent cognitive decline or improve memory, or containing docosahexaenoic acid ("DHA"), including, but not limited to, BrainStrong Adult. Covered Product does not include infant formula or ingredients when sold specifically for use in infant formula.

5. "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 are 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.

6. "Endorsement" means as defined in 16 C.F.R. § 255.0.

7. "Food" and "drug" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

8. The term "including" in this order means "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.

10. "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.

I.
Prohibited Memory and Cognitive Decline Claims

IT IS ORDERED that Respondents and their officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, 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, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product:

A. improves memory in adults; or

B. prevents cognitive decline in adults,

unless the representation is non-misleading and, at the time of making such representation, Respondents possess and rely upon competent and reliable scientific evidence to substantiate that the representation is true. For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing that is sufficient in quality and quantity, based on standards generally accepted by experts in cognitive science, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be randomized, double-blind, and placebo-controlled; and be conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in cognitive science as relevant to an assessment of such testing, as set forth and described in the Part of this Order entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies, must be available for inspection and production to the Commission.

II.
Prohibited Health Benefit Claims

IT IS FURTHER ORDERED that Respondents and their officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, 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, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, other than representations covered under Part I of this order, about the health benefits, performance, safety, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, the Respondents possess and rely 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 that (1) have been conducted and evaluated in an objective manner by qualified persons; (2) 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 set forth in the Part of this Order entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies, are available for inspection and production to the Commission.

III.
Prohibited Representations Regarding Tests or Studies

IT IS FURTHER ORDERED that Respondents and their officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, 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, including through the use of a product name, word, phrase such as “clinically shown” or “clinically proven,” endorsement, depiction, illustration, trademark, or trade name:

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

B. That any benefits of such Covered Product are scientifically or clinically proven, including, but not limited to, that the Covered Product is clinically proven to improve memory in adults.

IV.
FDA Approved Claims

IT IS FURTHER ORDERED that nothing in this order shall prohibit Respondents from making any representation for:

A. Any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; or

B. Any product that is 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.
Record Keeping Requirements

IT IS FURTHER ORDERED that Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

A. All advertisements, labeling, packaging, 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.

VI.
Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents 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, including 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 any Respondent, or by any person or entity affiliated with or acting on behalf of any Respondent, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with any Respondent ("Respondent's affiliates"), (2) by the supplier or manufacturer of the product at issue, or (3) by a supplier to any 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 Respondents, Respondents 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 Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

VII.
Order Acknowledgements

IT IS FURTHER ORDERED that Respondents shall deliver a copy of this order to all current and future principals, officers, and directors, and to all current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this order. Respondents shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to such current

personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.
Compliance Notification

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change in the corporations that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; 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 business or corporate name or address. Provided, however, that, with respect to any proposed change in the corporation(s) about which Respondents learn less than thirty (30) days prior to the date such action is to take place, Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line i-Health, Inc., FTC File No. 122-3067. *Provided, however*, that, in lieu of overnight courier, notices may be sent by first class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

IX.
Compliance Reporting

IT IS FURTHER ORDERED that Respondents, within one hundred twenty (120) 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 compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

X.
Order Termination

This order will terminate on August 21, 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 Respondent 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 Respondents 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, Commissioner Ohlhausen dissenting and Commissioner McSweeny not participating.

Donald S. Clark
Secretary

SEAL:
ISSUED: August 21, 2014