

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill

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 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, 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 limited 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 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

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 of 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 not 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 shall be 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.

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

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

VIII.
Compliance Notification

