

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of i-Health, Inc. and Martek Biosciences Corporation File No. 122 3067

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from against i-Health, Inc. and Martek Biosciences Corporation (hereafter “the companies”).

The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves the companies’ advertising for the BrainStrong Adult dietary supplement containing algal docosahexaenoic acid (“DHA”), an omega-3 fatty acid. The Commission’s complaint alleges that, based primarily on a randomized, controlled trial called the “Memory Improvement with Docosahexaenoic Acid (DHA) Study” (the “MIDAS study”), the companies advertised that BrainStrong Adult improves memory and prevents cognitive decline in adults, and is clinically proven to improve memory in adults. Human cognitive function consists of at least five different types of memory, as well as non-memory abilities such as executive function, attention, processing speed, and reasoning. The MIDAS study objectively tested only two types of memory (episodic and working memory) and the cognitive ability of executive function, and was not designed to test DHA’s effect on cognitive decline in aging adults.

The complaint alleges that the companies violated Sections 5(a) and 12 of the Federal Trade Commission Act by making the unsubstantiated representation that BrainStrong Adult improves memory in adults. According to the complaint, the MIDAS study did not show that BrainStrong Adult improves working memory or the cognitive ability of executive function. In addition, results from the tests of episodic memory did not yield a pattern of statistically and clinically significant improvement in the DHA group relative to the placebo group. For the same reasons, the complaint also alleges that the companies violated Sections 5(a) and 12 by making the false or misleading representation that BrainStrong Adult is clinically proven to improve memory in adults.

Finally, the complaint alleges that the companies violated Sections 5(a) and 12 by making the unsubstantiated representation that BrainStrong Adult prevents cognitive decline in adults. According to the complaint, a subject’s performance on laboratory tasks that measure only one type of memory (*i.e.*, episodic) does not fully capture the overall state of his or her cognitive function, which includes other types of memory and non-memory cognitive abilities. In the MIDAS study, subjects treated with DHA for twenty-four weeks performed worse than placebo on a task of executive function, a non-

memory cognitive ability. Moreover, a twenty-four-week study is an insufficient duration to test the impact of DHA on cognitive decline. Because the placebo group in the MIDAS study showed no evidence of cognitive decline, the study could reach no conclusion about DHA's ability to prevent or slow that condition.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. For purposes of the order, "Covered Product" means any dietary supplement, food, or drug promoted to prevent cognitive decline or improve memory, or containing DHA, including, but not limited to, BrainStrong Adult, except for infant formula or ingredients when sold specifically for use in infant formula. As additional fencing-in relief, the order requires the companies to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that they conduct or sponsor on the Covered Product.

Part I of the proposed order prohibits any representation that the Covered Product improves memory or prevents cognitive decline in adults, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must 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. The testing must have been conducted by qualified researchers, and have been randomized, double-blind, and placebo-controlled. In addition, the companies must maintain all underlying or supporting data that cognitive science experts generally would accept as relevant to an assessment of such testing.

Part II of the proposed order prohibits any representation about the health benefits, performance, safety, or efficacy of the Covered Product, unless it is non-misleading and supported by 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 have been conducted by a qualified person in an objective manner and are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of a human clinical trial, the companies must maintain all underlying or supporting data and documents that experts in the field generally would accept as relevant to an assessment of such testing.

Part III of the proposed order prohibits the companies from misrepresenting, including through the use of a product name, word or phrase such as "clinically shown" or "clinically proven," endorsement, depiction, illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, including misrepresenting that the benefits of the product are clinically proven or that the product is clinically proven to improve memory in adults.

Part IV of the proposed order provides a safe harbor for representations permitted under any tentative or final standard promulgated by the Food and Drug Administration (“FDA”), any new drug application approved by the FDA, or FDA regulations pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997.

Part V contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III of the order.

Triggered when the human clinical testing requirement in either Part I or II applies, **Part VI** of the proposed order requires the companies to 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, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test’s researchers. There is an exception for a “Reliably Reported” test defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by any proposed respondent or supplier. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Parts VII through IX of the proposed order require the companies to: deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order’s terms in any way.