

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

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

<p>In the Matter of</p> <p>I-HEALTH, INC., a corporation, and</p> <p>MARTEK BIOSCIENCES CORP., a corporation.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>DOCKET NO. C-4486</p>
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COMPLAINT

The Federal Trade Commission (“FTC” or “Commission”), having reason to believe that i-Health, Inc. and Martek Biosciences Corporation (“Respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent i-Health, Inc. is a Delaware corporation with its principal office or place of business at 55 Sebeth Drive, Cromwell, Connecticut 06416. i-Health, Inc. was formerly known as Amerifit Brands, Inc. (also known as Amerifit, Inc.).

2. Respondent Martek Biosciences Corporation is 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. Since at least March 2011, Respondents have together labeled, advertised, promoted, offered for sale, sold, and distributed to consumers throughout the United States a dietary supplement branded as BrainStrong Adult, which contains, among other ingredients, docosahexaenoic acid (“DHA”), an Omega-3 fatty acid, from algal triglyceride oil. BrainStrong Adult is either a “food” or a “drug” as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

4. The acts and practices of Respondents, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

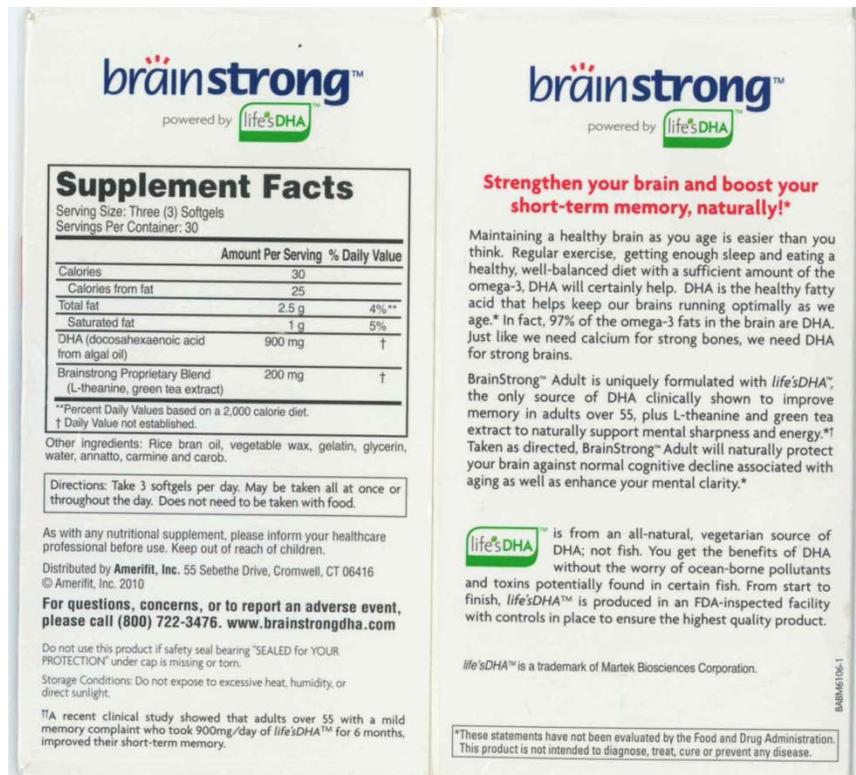
BrainStrong Adult

5. BrainStrong Adult is formulated for adults with a recommended dose of 900 mg of DHA per day and is marketed at a wide range of major retail stores, including, but not limited to, CVS Pharmacy, Walmart, Walgreens, and Rite Aid. BrainStrong Adult is also marketed through online vendors, such as www.drugstore.com and www.amazon.com. The retail price is approximately \$30 for a thirty-day supply.

6. Respondents have disseminated or caused to be disseminated advertisements for BrainStrong Adult, including, but not limited to, the attached Exhibits A through D. These advertisements contain the following statements and depictions, among others:

A. **Product Packaging:** BrainStrong Adult 90-Count Bottle





B. Product Packaging: BrainStrong Adult 120-Count Bottle



brainstrong™

Only BrainStrong Adult is clinically shown to improve memory*†

- **BrainStrong Adult** is uniquely formulated with *life'sDHA™*, the only source of DHA clinically shown to improve memory in adults over 55, plus L-theanine and green tea extract to naturally support mental sharpness and energy*†
- Taken as directed, **BrainStrong Adult** will naturally protect your brain against normal cognitive decline associated with aging as well as enhance your mental clarity*
- *life'sDHA™* is from an all-natural, vegetarian source of DHA, not fish. You get the benefits of DHA without the worry of ocean-borne pollutants and toxins potentially found in certain fish.

For more information, visit www.brainstrongdha.com

Why do our brains need DHA?
 DHA is the healthy fatty acid that is important for brain health and function throughout life. In fact, 97% of the omega-3 fats in the brain are DHA. Just like we need calcium for strong bones, we need DHA for strong brains. Because our bodies do not produce DHA omega-3, it must be consumed through food or supplements. Years ago Americans consumed plenty of omega-3 fats, but these days we do not — given our intake of highly processed foods, we need to add it to our diets.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Distributed by Ameritis, Inc.
 55 S. Westport Drive, Cromwell, CT 06416
 © Ameritis, Inc. 2011

For questions, concerns, or to report an adverse event, please call 1-800-722-3476
www.brainstrongdha.com

0 92961 02017 3

C. **Internet Website:** www.brainstrongdha.com (Exhibit A)

JUST SAY “NO” TO THE LOSS OF MEMORY.

* * *

THE MIDAS STUDY

Losing your memory as you age may be natural. But improving your memory can also be natural. New BrainStrong™ with *life'sDHA™*, is safe, natural and clinically shown to help protect against normal, cognitive decline as we age.†

THE STUDY THAT PROVED IT.

Adults 55+: The Memory Improvement with Docosahexaenoic Acid (DHA) Study, or MIDAS, was the first large, randomized and placebo-controlled study demonstrating the benefits of DHA in maintaining and improving brain health in

older adults. The study indicated that the use of DHA improves learning and memory recall in healthy aging adults with mild memory complaints.

IN OTHER WORDS:

MIDAS found that healthy people with memory complaints who took 900 mg/day algal DHA capsules for six months had almost double the reduction in errors on a test that measures learning and memory performance versus those who took a placebo, a benefit roughly equivalent to having the learning and memory skills of someone three years younger.

* * *

Conclusions:

- 900 mg/day algal DHA supplementation for 6 months resulted in a significant decrease of memory errors on a memory test as well as significant increases to verbal recognition memory scores.

* * *

A BATTLE PLAN:

We now have clinical evidence to indicate that 900 mg/day of algal DHA improves memory in aging adults.

†A recent clinical study showed that adults over 55 with a mild memory complaint, who took 900mg/day of life'sDHA™ for 6 months, improved their short-term memory.

* * *

BrainStrong Adult is a daily brain health supplement for adults of all ages containing 900mg/serving of a DHA omega-3 fatty acid, which helps protect the brain against normal cognitive decline as we age.

D. Television Advertisement: "Forget Me Not" (Exhibit B: CD and storyboard excerpt)



(Music)
WOMAN (VOICE OVER): What did I walk into this room for?



DOG (V.O.): Your sunglasses.



WOMAN (V.O.): I'm not leaving until I remember why I came in here.



VOICE OVER: Need a memory boost?
Introducing BrainStrong...

Text: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



with life's DHA, the natural, essential nutrient for a healthy brain.



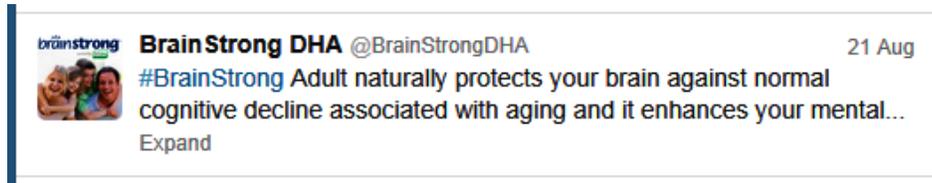
Clinically shown to improve adult memory.

E. Internet Website: Facebook (Exhibit C) (DSM-FTC-1100)

“BrainStrong Adult is a new daily brain health supplement for adults containing 900mg/serving of a DHA omega-3 fatty acid, which helps protect the brain against normal cognitive decline as we age.”

F. Internet Advertisements: Twitter

i. Tweets from December 18, October 24, and August 21, 2012



ii. Exhibit D (DSM-FTC-1030)

31 Mar [BrainStrong Twitter image] **BrainStrong DHA @BrainStrongDHA**
Did you know you can continue learning into your 80s? And BrainStrong has been shown to increase memory in adults 55+! **#BrainStrongChamp**

7. There are several types of human memory. Episodic memory is the recollection of specific personal events linked to a time and place. It can be verbal, as in remembering a conversation or a list of grocery items, or nonverbal, as in recalling a major life event (*e.g.*, the birth of a child) or where one left an object. Episodic memory can be of short (minutes) or long (years) duration. The scenario depicted in Exhibit B (a woman not recalling the reason she entered a room – to find her sunglasses) is an example of an episodic memory failure over a short duration. Humans also possess sensory memory (*e.g.*, residual sensory impressions of visual stimuli or sounds), working memory (the short-term mental manipulation of information, such as numbers), semantic memory (general knowledge about the world, such as facts, concepts, and vocabulary), and procedural memory (learned skills, like riding a bike).

8. Human cognitive function includes not only the different types of memory, but also non-memory abilities such as executive function, attention, processing speed, and reasoning.

9. The MIDAS study referred to in Exhibit A objectively tested only two types of memory – episodic and working – and the cognitive ability of executive function. In addition, according to the authors of the MIDAS study, the study “was not designed to assess long term effects of DHA on cognitive decline rates,” and although “DHA is potentially beneficial for prevention of cognitive decline[, it] will need confirmation with long-term prevention trials.”

Count I
Unsubstantiated Memory Improvement Claim

10. In connection with the advertising, promotion, offering for sale, or sale of BrainStrong Adult, Respondents have represented, directly or indirectly, expressly or by implication, that BrainStrong Adult improves memory in adults.

11. The representation set forth in Paragraph 10 was not substantiated at the time the representation was made. The MIDAS study did not show that BrainStrong Adult improved performance on non-episodic memory tasks. In addition, the MIDAS study employed three types of laboratory tasks to test different, but interrelated, aspects of episodic memory – visuospatial memory, visual pattern recognition memory, and visual-verbal memory. Results from these tasks did not yield a pattern of statistically and clinically significant improvement in the DHA group relative to the placebo group. Whether analyzed separately or as a composite, the effect size of any statistically significant, between-group difference was trivial, and no

evidence showed that any such difference correlated with improvement in everyday episodic memory tasks outside the laboratory, such as the ability to remember the location of one's sunglasses or why one entered a room.

Count II
Unsubstantiated Prevention of Cognitive Decline Claim

12. In connection with the advertising, promotion, offering for sale, or sale of BrainStrong Adult, Respondents have represented, directly or indirectly, expressly or by implication, that BrainStrong Adult prevents cognitive decline in adults.

13. The representation set forth in Paragraph 12 was not substantiated at the time the representation was made. 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 MIDAS showed no evidence of cognitive decline, the study could reach no conclusion about DHA's ability to prevent or slow that condition.

Count III
False Establishment Claim about Memory Improvement

14. In connection with the advertising, promotion, offering for sale, or sale of BrainStrong Adult, Respondents have represented, directly or indirectly, expressly or by implication, that BrainStrong Adult is clinically proven to improve memory in adults.

15. In fact, BrainStrong Adult is not clinically proven to improve memory in adults. Therefore, the representation set forth in Paragraph 14 was, and is, false or misleading.

Violations of Sections 5 and 12

16. The acts and practices of Respondents as alleged in this Complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, this twenty-first day of August, 2014, has issued this complaint against the Respondents.

By the Commission, Commissioner Ohlhausen dissenting and Commissioner McSweeney not participating.

Donald S. Clark
Secretary