

Complaint

IN THE MATTER OF

I-HEALTH, INC.**AND****MARTEK BIOSCIENCES CORP.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4486; File No. 122 3067**Complaint, August 21, 2014 – Decision, August 21, 2014*

This consent order addresses i-Health, Inc.'s and Martek Biosciences Corporation's advertising for the BrainStrong Adult dietary supplement containing algal docosahexaenoic acid ("DHA"), an omega-3 fatty acid. 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 and prevents cognitive decline in adults. The consent order prohibits any representation about the health benefits, performance, safety, or efficacy of any dietary supplement, food, or drug promoted to prevent cognitive decline or improve memory, or containing DHA, 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.

Participants

For the *Commission*: Victor DeFrancis, Keith Fentonmiller, and Edwin Rodriguez.

For the *Respondents*: Charles Dickinson, Martin Hahn, and Corey Roush, Hogan Lovells US LLP; Jason Stephans, In-House Counsel.

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:

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1. Respondent i-Health, Inc. is a Delaware corporation with its principal office or place of business at 55 Sebethe 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:

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



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b. **Product Packaging:** BrainStrong Adult 120-Count Bottle

Complaint

- 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

Complaint

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.

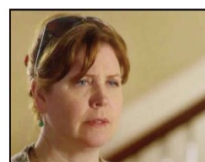
d. **Television Advertisement:** “Forget Me Not”
(Exhibit B: CD and storyboard excerpt)



(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. The 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.

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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:** Twitteri. Tweets from December 18, October 24, and August 21, 2012ii. 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**

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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

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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.

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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.

Complaint

Exhibit A

DHA for Adults 55+ | DHA Omega-3 for Brain & Memory Health | BrainStrong

Buy Online Find a Retailer Testimonials

brainstrong powered by **lifeDHA**

Products Expectant Moms Toddlers Kids Adults Nourish the Brain

Adults

DHA FOR ADULTS 55+

[THE MIDAS STUDY](#)

[BRAINSTROG ADULT](#)

[Life's DHA: WHAT'S THE STORY?](#)



DHA FOR ADULTS 55+

LIKE BONES NEED CALCIUM, BRAINS NEED DHA.

JUST SAY "NO" TO THE LOSS OF MEMORY.

Yes, a certain degree of memory loss and decline in cognitive function may be considered a normal part of aging. And brain health, including memory, is often listed as one of the top health-related concerns of aging populations in the U.S. and other countries.

But DHA is brain nutrition. And since our bodies don't efficiently make DHA, we need to consume it through food, beverages or supplements to keep our brains functioning to the best of their ability.

Yet most American adults age 55+ consume less than 100 mg of DHA daily, which is not enough.

The U.S. Institute of Medicine recommends adults take up to 160 mg/day DHA+EPA daily for general health. Numerous studies on safety and efficacy of DHA specifically at doses ranging from 25-5000 mg/day have shown no adverse effects.

Assuming you want to stay ahead, the question is how to improve your memory? Will you change your diet by adding DHA-rich food or will you take a DHA supplement?



You and 122 others like this. 122 people like this. Sign Up to see what your friends like.

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

**Highest level of DHA among leading Prenatal brands.

Exhibit A

http://brainstrongdha.com/adults/dha_for_adults[1/8/2013 9:21:03 AM]

Complaint

The MIDAS Study | Memory Improvement with DHA Study | DHA and Memory Loss

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[Products](#)
[Expectant Moms](#)
[Toddlers](#)
[Kids](#)
[Adults](#)
[Nourish the Brain](#)

Adults

[DHA FOR ADULTS 55+](#)

[THE MIDAS STUDY](#)

[BRAINSTRONG ADULT](#)

[life'sDHA: WHAT'S THE STORY?](#)



PLAY THE BRAIN GAME!

BRAINSTRONG IS ON FACEBOOK



LIKE BRAINSTRONG

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.

The DHA was well-tolerated and subjects taking the DHA also experienced a lower heart rate, providing a significant cardiovascular benefit.

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.
- DHA supplementation doubled plasma DHA levels. Higher plasma and red blood cell levels of DHA are associated with better cognitive function.
- DHA supplementation significantly decreased heart rate compared to placebo over the 24-week supplementation, providing a cardiovascular benefit consistent with previously published studies in humans.

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.*



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Exhibit A

http://www.brainstrongdha.com/adults/the_midas_study/ [1/4/2013 4:52:28 PM]

Complaint

Buy BrainStrong Adult DHA Omega-3 Products | Memory Improvement Supplements

Buy Online Find a Retailer Testimonials

brainstrong powered by **life'sDHA**

Products Expectant Moms Toddlers Kids Adults Nourish the Brain

Products

[BRAINSTRONG PRENATAL](#)

[BRAINSTRONG TODDLER](#)

[BRAINSTRONG KIDS](#)

BRAINSTRONG ADULT

BRAINSTRONG IS ON FACEBOOK

facebook

LIKE BRAINSTRONG

119 people like this. Sign up to see what your friends like.

brainstrong ADULT

CLINICALLY SHOWN TO IMPROVE 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.* BrainStrong Adult contains life'sDHA, the premium DHA, the only brand of DHA shown in a clinical study to improve memory.*†

†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.

More Information

[Product Facts and Directions for Use](#)

[Frequently Asked Questions](#)

Health Benefit

DHA is important for healthy brain and eye development and function* and has been shown to support heart health from infancy through adulthood.* Just as calcium is essential for building strong bones, DHA ensures that the cells in the brain, retina, heart, and other parts of the nervous system develop and function properly.* In order to ensure optimal development and function, we must continuously replenish the DHA in our bodies by getting enough of this important fatty acid in our diets.

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*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.
**Highest level of DHA among leading prenatal brands.

Exhibit A

http://www.brainstrongdha.com/products/brainstrong_adult[1/4/2013 4:50:15 PM]

Complaint

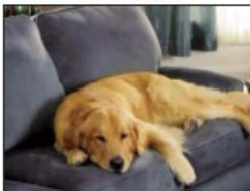
Exhibit B**Competitrack**

Advertiser: BrainStrong
Product: BrainStrong DHA
Title: Forget Me Not
Ad Code: BRSTPM-0005

First Date: 06/27/11
Source: New York City
Length: 30
New/Recut: New



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



DOG (V.O.): Your sunglasses.



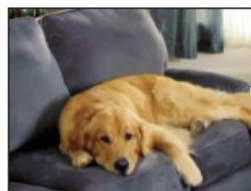
WOMAN (V.O.): I'm not leaving until I remember why I came in here.



DOG (V.O.): They're on your head.



WOMAN (V.O.): Maybe if I go out and come back in I'll remember.



DOG (V.O.): Yeah, that never works.



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

Test: 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.



WOMAN (V.O.): Can you tell me why I came in here?
DOG (V.O.): You never listen to me.



V.O.: New BrainStrong natural DHA supplement.



Nourish your brain.
(Fade out)

Test: brainstrongdha.com
DHA is DHA & Trademark Of Merck BioScience Corporation.

Exhibit B

- Tapes and MPEGs can be ordered by contacting us at 718.482.4211 -

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Exhibit C

<http://www.facebook.com/?sk=welcome>

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5/14/2012 12:50 PM

DSM-FTC-1100

Complaint

Exhibit D

BrainStrong DHA (brainstrongdha) on Twitter

<https://twitter.com/#!/BrainStrongDHA>

 **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

[Expand](#) [Collapse](#)

- [Reply](#)
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- [FavoritedFavorite](#)

 **BrainStrong DHA** @BrainStrongDHA

The old adage that you are only using 10% of your brain isn't true; every part of the brain has a known function. #BrainStrongChamp

[Expand](#) [Collapse](#)

- [Reply](#)
- [Delete](#)
- [FavoritedFavorite](#)

 **BrainStrong DHA** @BrainStrongDHA

Find out if your child is getting enough DHA: ow.ly/9HV8g #BrainHealth

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- [Reply](#)
- [Delete](#)
- [FavoritedFavorite](#)

 **Lifehacker** @lifehacker

How to train your brain and boost your memory like a USA memory champion: lifehack.kr/HxZSNw

Retweeted by [BrainStrong DHA](#)

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- [RetweetedRetweet](#)
- [Delete](#)
- [FavoritedFavorite](#)

Decision and Order

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:

3. Respondent i-Health, Inc. is a Delaware corporation with its principal office or place of business at 55 Sebethe Drive, Cromwell, Connecticut 06416.
4. 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

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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.

5. 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:

- A. Unless otherwise specified, “Respondents” means i-Health, Inc. and Martek Biosciences Corporation, and their successors and assigns.
- B. DSM Nutritional Products, LLC is a successor of Martek Biosciences Corporation.
- C. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “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.
- E. “Dietary supplement” means:
 1. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or
 2. any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or

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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.

- F. “Endorsement” means as defined in 16 C.F.R. § 255.0.
- G. “Food” and “drug” mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.
- H. The term “including” in this order means “without limitation.”
- I. 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.
- J. “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,

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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

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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.

Decision and Order

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.

Decision and Order

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.

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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

Decision and Order

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:

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- 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 McSweeney not participating.

**Statement of Chairwoman Edith Ramirez and
Commissioner Julie Brill**

We write to explain our support for the complaint and order imposed against respondents i-Health, Inc. and Martek Biosciences Corporation (collectively, “i-Health”) with respect to advertising claims that their BrainStrong Adult dietary supplement improves adult memory and is clinically proven to do so. Section 5 of the FTC Act requires that advertisers have a reasonable basis for the claims they make to ensure that their claims are truthful and non-deceptive.¹ We have reason to believe that i-Health fell short of this standard.

¹ *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984)) (“*Substantiation Statement*”) (“[W]e reaffirm our commitment to the

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i-Health advertises a dietary supplement, BrainStrong Adult, containing docosahexaenoic acid (“DHA”), with broad and prominent claims that the product is “[c]linically shown to improve memory.” Its advertising also makes the general efficacy claim that BrainStrong improves memory. Consumers would likely have reasonably interpreted these claims broadly to include a wide variety of promises of real-life improvements in memory, such as the ability to remember the location of one’s sunglasses or why one entered a room – which is the precise scenario depicted in i-Health’s television ad.² We do not believe that i-Health possessed the evidence necessary to back up such reasonable interpretations by consumers. Accordingly, we allege that i-Health’s efficacy claim was unsubstantiated and that its establishment claim was false and misleading.³

i-Health’s establishment claim that BrainStrong Adult is clinically proven to improve adult memory requires, by its own terms, a well-controlled human clinical study.⁴ Its efficacy claim about its dietary supplement must be supported by competent and reliable scientific evidence.⁵ In support of these claims, i-Health

underlying legal requirement of advertising substantiation – that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.”), *aff’d*, 791 F.2d 189, 193 & 196 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

2 See FTC, *Dietary Supplements: An Advertising Guide for Industry* 3-4 (Apr. 2001) (“*Dietary Supplements Guide*”), available at <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry> (“When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation.”); see also *id.* at 12.

3 The Commission also alleges that i-Health made the unsubstantiated claim that BrainStrong prevents cognitive decline in adults. Because the Commission has unanimously voted in favor of this allegation, we do not address it here.

4 *Substantiation Statement* at 839 (“When the substantiation claim is express (e.g., ‘tests prove,’ ‘doctors recommend,’ and ‘studies show’), the Commission expects the firm to have at least the advertised level of substantiation.”); *Removatron Int’l Corp.*, 111 F.T.C. 206, 297-99 (1988) (“If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim’s truth.”), *aff’d*, 884 F.2d 1489 (1st Cir. 1989).

5 *Dietary Supplements Guide* at 9.

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relies primarily on a double-blind, placebo-controlled clinical study published in a peer-reviewed journal – the Memory Improvement with Docosahexaenoic Acid Study (“MIDAS study”). The study purports to show that DHA “improves episodic memory” and “memory function.” The MIDAS study’s principal investigator and author was an employee of respondent Martek.⁶

As an initial matter, regardless of the methodology and purported findings of the MIDAS study, the first question we ask is what the study was designed to measure and demonstrate. Stated differently, and more directly for our purposes, does the study, assuming it was well-conducted, substantiate i-Health’s broad claims that BrainStrong improves memory and that it was “clinically shown” to do so? Contrary to the view of Commissioner Ohlhausen, we do not think it does.

As detailed in the complaint, there are several types of human memory, including episodic memory, sensory memory, working memory, semantic memory, and procedural memory. Importantly, the MIDAS study tested tasks associated with only two types of memory: episodic memory, the recollection of specific personal events linked to a time and place, such as where someone left her car keys; and working memory, the short-term mental manipulation of information, such as the ability to follow a story or discussion. Notably, the study reports only a very small improvement from BrainStrong in relation to episodic memory – the positive result was essentially limited to performance on a single test of one of three types of episodic memory that were measured (visuospatial). The study did not reveal any improvement in working memory. In light of the narrow scope of the study and its limited results, we have reason to believe that i-Health’s marketing claims that BrainStrong improves “memory” broadly speaking would likely mislead consumers, as there is no basis to conclude that it has any impact whatsoever on other important facets of memory, such as the ability to remember the meaning of words (semantic memory) or to follow an exchange of

6 Karin Yurko-Mauro et al., *Beneficial Effects of Docosahexaenoic Acid on Cognition in Age-Related Cognitive Decline*, 6 *Alzheimer’s & Dementia* 456 (2010).

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dialogue (working memory). This alone would be reason enough for us to conclude that the MIDAS study does not adequately substantiate i-Health's general memory improvement claims.

But our concerns extend even further. As we have also alleged in the complaint, the MIDAS study did not show a pattern of statistically and clinically significant improvements on the episodic memory tasks among subjects who took BrainStrong's DHA, relative to the placebo group. Specifically, it failed to show meaningful, statistically significant improvements on two of the three episodic memory tasks measured. Further, it failed to demonstrate that the very small, statistically significant improvement on one of those tasks that it did report correlates with improvements in memory tasks outside of the laboratory.⁷ We believe that reasonable consumers would likely be misled that BrainStrong will result in the kinds of real-life improvements depicted in i-Health's advertising.

It is correct, as Commissioner Ohlhausen notes in her dissent, that some of the statements made by the study's authors in the "Results" and "Discussion" sections of the MIDAS study use language similar to that in i-Health's memory improvement claims. However, we disagree that the Commission must accept at face value these statements as supportive of the claims in i-Health's advertising. Doing so would be inconsistent with the Commission's obligation to assess the quality and reliability of the scientific evidence underlying challenged advertising claims.⁸ Our conclusions are based on extensive consultations with experts in the cognitive science and biostatistics fields. Consistent with the requirements of Section 5 and our past practice,⁹ we undertook

⁷ See *Dietary Supplements Guide* at 12 ("Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.").

⁸ Commissioner Ohlhausen also observes that the complaint does not take issue with how i-Health conducted the clinical testing component of the trial, *i.e.*, that it was a large, multi-center trial that was randomized, placebo-controlled, and double-blinded. However, sometimes such studies ultimately yield inconclusive or weak findings, as was the case with the MIDAS study.

⁹ See, *e.g.*, *Schering Corp.*, 118 F.T.C. 1030, 1084, 1095 (1994). See also *Unither Pharma, Inc.*, 136 F.T.C. 145, 161 (2003).

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an evaluation of the results of the MIDAS study to assess whether they substantiated i-Health's advertising claims and did not simply defer to the authors' interpretations of their results.¹⁰

For all of the foregoing reasons, we have reason to believe that i-Health lacked adequate substantiation for the broad marketing claims that BrainStrong Adult improves adult memory, that i-Health's clinical-proof claims are false and misleading, and that the relief set forth in the proposed order is appropriate.

¹⁰ In addition to the MIDAS study, our experts in the cognitive science and biostatistics fields also reviewed the totality of other evidence that i-Health proffered on DHA and memory, finding those results to be inadequate to back i-Health's claims as well.

Dissenting Statement

**Separate Statement of Commissioner Maureen K. Ohlhausen
Dissenting in Part**

The Commission has long interpreted Section 5 of the FTC Act¹ to require an advertiser to have a reasonable basis for making an objective claim about its product.² As we execute this mandate, we must be mindful of what we are trying to accomplish, however. As former FTC Chairman Robert Pitofsky stated, the overall goal of evaluating advertising claims is not “a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn will facilitate an efficient and reliable competitive market process.”³

I dissent in part from today’s action because it imposes an unduly high standard of substantiation on a safe product. This unduly high standard not only risks denying consumers useful information in the present but may also, in the long term, diminish incentives to conduct research on the health effects of foods and dietary supplements and reduce the incentives of manufacturers to introduce such products.⁴ The majority’s approach may ultimately undermine an efficient and reliable competitive market process and make consumers worse off.⁵

1 15 U.S.C. § 45(a).

2 FTC Policy Statement Regarding Advertising Substantiation (appended to *Thompson Med. Co., Inc.*, 104 F.T.C. 648, 840 (1984)).

3 Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV. 661, 671 (1977).

4 See Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc., et al.*, FTC Docket No. C4456, at 2 (Jan. 7, 2014) (“Although raising the requirement for both the number and the rigor of studies required for substantiation for all health- or disease-related claims may increase confidence in those claims, the correspondingly increased burdens in time and money in conducting such studies may suppress information that would, on balance, benefit consumers.”).

5 See *id.* (“If we demand too high a level of substantiation in pursuit of certainty, we risk losing the benefits to consumers of having access to information about emerging areas of science and the corresponding pressure on firms to compete on the health features of their products.”); FTC Staff Comment Before the Food and Drug Administration In the Matter of Assessing

Dissenting Statement

The complaint in this matter challenges the efficacy claim that BrainStrong Adult (a DHA supplement) improves memory in adults and the establishment claim that BrainStrong Adult is clinically proven to improve memory in adults.⁶ Advertisers must support claims of efficacy of dietary supplements with “competent and reliable scientific evidence.”⁷ For establishment claims, where advertisements refer to a certain level of support, advertisers “must be able to demonstrate that the assertion is accurate [and] have the level of support that they claim, expressly or by implication, to have.”⁸

In this matter, the defendant offers as the primary substantiation for its claims the MIDAS study, a placebo-controlled, randomized, double-blind, parallel, multi-center, six-month, peer-reviewed, journal-published study of 485 subjects with statistically significant results.⁹ Specifically, the MIDAS study concluded:

Consumer Perceptions of Health Claims, Docket No. 2005N-0413, at 5-6 (2006) (noting the FTC’s advertising enforcement seeks to avoid “unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions.”) available at <http://www.ftc.gov/be/V060005.pdf>.

6 The complaint also challenges the efficacy claim that BrainStrong Adult prevents cognitive decline. I agree with the majority that the proffered study does not support this claim.

7 The FTC’s *Dietary Supplements: An Advertising Guide for Industry* defines competent and reliable scientific evidence as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” It further states that well-controlled human clinical trials are the “most reliable form of evidence.” See *Dietary Supplements: An Advertising Guide for Industry* at 9 (“*Dietary Supplements Guide*”), available at <http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf>.

8 *Id.*

9 See Karin Yurko-Mauro *et al.*, *Beneficial Effects of Docosahexaenoic Acid on Cognition in Age-Related Cognitive Decline*, 6 ALZHEIMER’S & DEMENTIA 456 (2010) (“MIDAS study”).

Dissenting Statement

- “This clinical study demonstrated that 900 mg/d of DHA supplementation improved episodic memory and learning in healthy, older adults with mild memory complaints.... The DHA effects are significant in that they represent an objective demonstration of improved memory in [age-related cognitive decline].”¹⁰
- “Our results are the first to clinically confirm that DHA significantly improves episodic memory and learning functions in healthy adults with [age-related cognitive decline].”¹¹
- “Our study results demonstrate that DHA is well tolerated and may have significant positive effect on gradual memory loss....”¹²

These conclusions match up well with the “improves memory” efficacy claim and the “clinically proven to improve memory” establishment claim.¹³ Thus, I believe this study, in the context of other supporting studies involving DHA and memory,¹⁴ provides a reasonable basis for the “improves memory” claims.¹⁵

¹⁰ *Id.* at 461.

¹¹ *Id.* at 463.

¹² *Id.*

¹³ BrainHealth Adult product packaging also included language stating, “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.”

¹⁴ Martek cited many studies, including: a wide body of animal and cell culture studies that are consistent with the importance of DHA in cognitive function and suggest a potential mechanism for DHA’s ability to support memory; numerous epidemiological studies identifying a correlation between DHA consumption and cognitive function; multiple clinical trials with generally supportive (although not wholly consistent) results; and seven reviews by independent expert bodies confirming the importance of DHA in supporting cognitive function. Not all of these studies are squarely on point, and some of them contain methodological weaknesses or inconclusive results. As such, their probity varies, but taken together they are supportive of DHA’s positive role in brain function. The FTC must evaluate the well-conducted,

Dissenting Statement

The complaint offers two reasons why the MIDAS study, despite being well-conducted and having statistically significant results, does not substantiate Martek's claims for BrainStrong Adult. First, the complaint argues that the "improves memory" claim is unsubstantiated because the MIDAS study did not show that BrainStrong Adult improved performance for all types of memory. However, the MIDAS study did demonstrate a statistically significant improvement in performance on episodic memory tasks. An improvement in episodic memory is indeed an improvement in memory, and the claim accurately conveys the study's findings in consumer vernacular.

Second, instead of criticizing the study's methodology, the complaint criticizes its conclusions. The complaint asserts that the MIDAS study "did not yield a pattern of statistically and clinically significant improvement" in memory.¹⁶ This conclusion is based on the opinion of experts retained by FTC

statistically significant MIDAS study within the totality of this supportive evidence. See *Dietary Supplements Guide* at 14 ("Studies cannot be evaluated in isolation. The surrounding context of scientific evidence is just as important as the internal validity of individual studies.").

15 Because the claims at issue here closely parallel the conclusions of the MIDAS study, this case differs from others where companies possessed well-conducted clinical trials yielding statistically significant results but made claims beyond the trials' ability to support. Cf. *Nestle HealthCare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (defendant claimed its product reduced the duration of acute diarrhea in children up to the age of thirteen; studies only applied to infants and could not be extrapolated to older children); *Kellogg Co.*, FTC Docket No. C-4262 (2009) (defendant claimed that children who ate Frosted MiniWheats for breakfast were "nearly 20%" or "up to 18%" more attentive three hours later than children who ate nothing; study calculated average increased attention as ~10% and over half of children showed no benefit from eating the cereal).

16 It is undisputed that the MIDAS study's primary endpoint (the CANTAB Paired Associate Learning, or "PAL," test) yielded statistically significant results, with a p-value of 0.032. As the Commission has stated, "significance with a p-value that is less than or equal to 0.05 is the recognized standard to show that a study's hypothesis has been proven." *POM Wonderful LLC*, Opinion of the Commission, 2013 FTC Lexis 6 at *77 (2013). Furthermore, the MIDAS study demonstrated that the difference in PAL scores between the test group and the placebo group was equivalent to a net 3.4-year improvement in performance, offering evidence of a clinically significant result.

Dissenting Statement

staff. The eight MIDAS study co-authors clearly disagree with this conclusion, as demonstrated by their own conclusions in the study.

The fact that some experts may disagree with the conclusions of a well-conducted study does not render that study unreliable or incompetent, nor make claims based on the study unsubstantiated. Specifically, Martek's reliance upon the MIDAS study, which was both well-conducted and consistent with other research, is not rendered unreasonable by the existence of some disagreement among experts. Indeed, "some disagreement" is the usual state of science.¹⁷

¹⁷ "The game of science is, in principle, without end. He who decides one day that scientific statements do not call for any further test, and that they can be regarded as finally verified, retires from the game." Karl Popper, *THE LOGIC OF SCIENTIFIC DISCOVERY* 32 (Taylor & Francis Group, 2005).

Concurring Statement

Concurring Statement of Commissioner Joshua D. Wright

As set forth in the Commission’s complaint, i-Health, Inc. and Martek Biosciences Corporation (i-Health) marketed a dietary supplement branded as BrainStrong Adult, which contains docosahexaenoic acid (DHA). In its advertising and marketing, i-Health represented, among other things, that BrainStrong Adult improves memory in adults.¹

As articulated in the complaint, these representations included a general memory improvement claim as well as a specific “episodic” memory improvement claim. I write separately to explain why, in my view, the Memory Improvement with Docosahexaenoic Acid Study (the MIDAS study) does not provide evidence sufficient to substantiate either of those claims.

First, the MIDAS study was not designed to evaluate all the types of memory that would be encompassed within a general memory claim.² As set forth in the complaint, there are several types of human memory, including episodic, sensory, working, semantic, and procedural. Although the MIDAS study included one test of working memory, which found no benefit from supplementation, the study’s focus was episodic memory. Therefore, to the extent that consumers took away an understanding that BrainStrong Adult would improve general memory, rather than a single dimension of human memory, that claim was unsubstantiated.

Second, the MIDAS study does not adequately substantiate even a narrower claim of improving episodic memory – for example, that BrainStrong Adult would help consumers recall where they had just left their keys or the reason they left one room to walk into another room. It is correct the MIDAS study was a well-designed attempt to evaluate improvement in episodic memory.³ The shortcoming of the MIDAS study as it relates to

1 Complaint at ¶ 10.

2 Complaint at ¶¶ 7 and 11.

3 The study was well designed in the sense that it was a randomized, double-blinded, placebo-controlled evaluation of multiple measures of episodic memory.

Concurring Statement

substantiation is not study design or methodology but rather that, put simply, its results were inconsistent and insufficiently robust to support claims about noticeable improvement in everyday memory along the lines of the television ad.

Episodic memory is a cognitive construct that encompasses the ability to recall specific autobiographical or personal events or “episodes,” as well as the time and place those events occurred. Episodic memories have one or more components (e.g., visual, visuospatial, verbal, auditory, and temporal) and are formed in the brain’s hippocampus after it interacts with one or more other brain regions. Identifying and isolating episodic memory can be especially difficult because of the potential influence of interactions with other brain regions, which may make it difficult to know whether and to what extent an improvement in test performance was due to changes to hippocampal function.

Consequently, in order to assess changes in episodic memory, cognitive experts generally conduct studies employing multiple measures of episodic memory. Laboratory tests of episodic memory probe hippocampal function via different modalities (e.g., visual, auditory, verbal, and tactile) and cognitive tasks (pattern recognition, visuospatial memory, verbal recall). Cognitive experts then consider the results of the different tests together, which reduces the impact of the various confounding influences that are associated with each individual test. This standard approach reduces the likelihood that idiosyncrasies in the design or administration of any one test will lead to an erroneous conclusion.⁴

Importantly, cognitive experts would generally accept that the observed effects from the intervention under study reflect changes to episodic memory rather than the influence of other neural pathways or a spurious correlation, when the multiple measures

4 Michael S. Humphreys et al., *Measuring Episodic Memory: A Novel Approach with an Indefinite Number of Alternative Forms*, 24 APPL. COGNIT. PSYCHOL. 1080, 1081 (2010) (“[t]he use of multiple tasks provides some insurance against the possibility that different neurological substrates are involved in at least some tasks commonly considered episodic.”) (citing Norman & O’Reilly, 2003).

Concurring Statement

show a consistent trend in favor of treatment. By contrast, cognitive experts evaluating an intervention that generates a small but statistically significant effect for one task but not the other two would generally conclude the collective results are insufficient to demonstrate improved episodic memory.

The MIDAS study properly 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.⁵ However, because the results of the three laboratory tasks, when evaluated together, did not consistently trend in support of improved episodic memory, the MIDAS study is not sufficient to substantiate i-Health's improved episodic memory claim.

⁵ Complaint at ¶ 11.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

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)

Analysis to Aid Public Comment

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

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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.

Analysis to Aid Public Comment

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.

Complaint

IN THE MATTER OF

**ACTAVIS PLC
AND
FOREST LABORATORIES, INC.****CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT**

*Docket No. C-4474; File No. 141 0098
Complaint, June 30, 2014 – Decision, August 29, 2014*

This consent order addresses the \$25 billion acquisition by Actavis plc of certain assets of Forest Laboratories, Inc. The complaint alleges that the acquisition violates Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in the markets for (1) generic diltiazem hydrochloride extended release capsules (AB4) (generic Tiazac), (2) generic ursodiol tablets, and (3) generic propranolol hydrochloride extended release capsules, as well as the future relevant market of lamotrigine orally disintegrating tablets and its generic equivalent. The consent order requires the parties to: (1) return all of Forest's rights and assets related to generic diltiazem hydrochloride (AB4) to Valeant Pharmaceuticals International, Inc., (2) divest all of Actavis' rights and assets to generic ursodiol and generic lamotrigine ODT to Impax Laboratories, Inc., and (3) divest all of Forest's rights and assets to generic propranolol hydrochloride to Catalent Pharma Solutions, Inc.

Participants

For the *Commission*: Christine E. Tasso and David Von Nirschl.

For the *Respondents*: Maria Raptis and Steven C. Sunshine, Skadden, Arps, Slate, Meagher & Flom LLP; Steven K. Bernstein and Ann Malester, Weil Gotshal & Manges LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Actavis plc ("Actavis"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent Forest Laboratories, Inc. ("Forest"), a