

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Federal Trade Commission,

Plaintiff,

vs.

NourishLife, LLC, and Mark Nottoli,
individually and as an officer of NourishLife,
LLC,

Defendants.

Case Number :

COMPLAINT FOR PERMANENT
INJUNCTION AND OTHER EQUITABLE
RELIEF

Plaintiff, the Federal Trade Commission (“FTC” or “Commission”), for its
Complaint alleges:

1. The FTC brings this action pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), to obtain a permanent injunction, rescission or reformation of contracts, restitution, the refund of monies paid, the disgorgement of ill-gotten monies, and other equitable relief for Defendants’ acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of children’s dietary supplements that purportedly maintain and develop speech and language capacity, including products sold under the brand names “speak” and “speak smooth,” herein referred to as “Speak.”

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. § 45(a) and 53(b).

3. Venue in the United States District Court for the Northern District of Illinois is proper under 28 U.S.C. § 1391(b)(1), (b)(2), (b)(3), (c)(1), (c)(2), and (d) and 15 U.S.C. § 53(b).

PLAINTIFF

4. Plaintiff FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, which prohibit, respectively, unfair or deceptive acts or practices, and false advertisements for food, drugs, devices, services, or cosmetics, in or affecting commerce. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission to initiate federal district court proceedings to enjoin violations of the FTC Act, and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies.

DEFENDANTS

5. Defendant NourishLife, LLC (“NourishLife”), also doing business as SpeechNutrients, Lifenutrients, PharmaOmega, and BeneOmega, is an Illinois limited liability company with its principal place of business at 272 East Deerpath Road, Suite 244, Lake Forest, IL 60045. NourishLife has marketed Speak in this District and throughout the United States. At all times material to this Complaint, acting alone, or in concert with others, NourishLife has labeled, advertised, marketed, distributed, or sold Speak to consumers throughout the United States.

6. Defendant Mark Nottoli (“Nottoli”) is the president and manager of NourishLife. Nottoli also is a majority owner of NourishLife, LLC through his ownership share in PharmaNutrients, Inc., of which he is the president and majority shareholder. At other times material to this Complaint, Nottoli was a majority owner of NourishLife through his ownership share in Revolution Works, Ltd., of which he was the president and the principal shareholder. He is an Illinois resident. At all times material to this Complaint, acting alone, or in concert with others, Nottoli has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of NourishLife, including the acts and practices set forth in this Complaint. In connection with the matters alleged herein, he transacts or has transacted business in this District and throughout the United States.

COMMERCE

7. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS’ COURSE OF CONDUCT

8. Speak is a dietary supplement containing Omega-3 and -6 fatty acids, Vitamin E, Vitamin K, and other ingredients. The Speak formula was developed by a research scientist employed by the Children’s Hospital and Research Center Oakland (“CHRCO”). On or around June 3, 2008, Defendants acquired the rights from CHRCO to market the Speak formula in the United States and world-wide.

9. Speak is available in liquid, softgel, and twist-off-capsule forms. Consumers can purchase a 60-count bottle of Speak softgels or capsules for approximately \$71.95, and a

30-tablespoon bottle of a liquid form called “Speak Smooth” for \$76.95. Defendants also offered one-box and two-box “Monthly Saver Plans,” where one or two boxes respectively shipped every thirty days for a recurring, monthly charge of approximately \$56.95 and \$54.95 per box for Speak softgels or capsules, and approximately \$61.95 and \$59.95 per bottle for Speak Smooth. Defendants recommend daily dosages between two to four capsules (one to two tablespoons of Speak Smooth) for toddlers and four to six capsules (two to three tablespoons of Speak Smooth) for older children, stating that increased benefits often are noted at higher dosages.

10. Since at least 2008, Defendants have labeled, advertised, marketed, distributed, and sold Speak to the public, directly and through a network of distributors, which, among others, includes physicians, therapists, and pharmacies. Defendants have advertised and promoted Speak through websites, such as SpeechNutrients.com and apraxiaresearch.com; search engine and display advertising; email; social media; direct mail; brochures; posters; product samples; and corporate sponsorships of various conferences on autism spectrum disorders and other childhood developmental conditions. Defendants have represented, among other things, through express and implied claims and consumer endorsements, that Speak develops and maintains normal, healthy speech and language capacity in children, including in children who have autism spectrum disorders and verbal apraxia (a condition in which a child’s brain has difficulty coordinating and directing movements required to form words), among other developmental conditions, and that Speak is clinically proven to produce these claimed results.

11. To induce consumers to purchase Speak, Defendants have disseminated or caused to be disseminated, advertisements and promotional materials for Speak, including but not limited to, the attached Exhibits A through L. These advertisements contained the following statements and depictions, among others:

A. www.SpeechNutrients.com, August 13, 2013 (excerpts attached as Exhibit A1-A9).

A1

[Home Page, excerpts]

Nutritional support for healthy speech development

SPEECHNUTRIENTS SPEAK™ SMOOTH

Speak™ Smooth is a nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance.

Mounting clinical evidence and hundreds of parental reports indicate this special blend of nutrients provides targeted benefits including:

- Nutritional support of verbal and motor skills

* * *

A2

[web page displayed upon clicking the tab labelled “Scientific Research”]

Research and Studies

PUBLISHED RESEARCH REGARDING THE ROLE OF OMEGA-3 AND VITAMIN E SUPPLEMENTATION IN CHILDREN: SCIENTISTS PROCLAIM OMEGA-3 SUPPLEMENTATION EFFECTIVE IN LEARNING.

A study published in the July/August 2009 journal *Alternative Therapies in Health and Medicine* describes the benefits noted in 97% of participants while taking a nutritional combination comprised of omega-3 and vitamin E.

* * *

The Oxford-Durham Schools Trials

Initial Trial results summary:

The most comprehensive and thorough trial yet of how omega-3 may be applied in the classroom . . .

* * *

A3

[Products Page]

* * *

SPEAK

Hypo-allergenic, Pediatrician Formulated

The pediatrician formulated omega-3 and vitamin E speech development formula that provides the precise serving and ratio of important nutrients needed for normal and healthy speech

* * *

A4

[Parents' testimonials, excerpts, in section entitled "Community Resources"]

Hear What Our Parents Have to Say

* * *

**WHEN I HEAR ELIZA TALK AT A REGULAR SPEED AND FLUENCY,
MY HEART PRACTICALLY SINGS.**

My 12-year-old daughter Eliza has always had a very laborious, uneven way of speaking As she enters adolescence her speech issues are exacerbating her social challenges, as her peers rarely have the patience to wait for her to complete a full sentence, let alone carry on a conversation . . . Late last spring Eliza & I had a brief consultation with a highly regarded nutritionists who recommended we try Speak. . . . [A]s we slowly increased the dose, I could no longer deny what I was seeing — she was having a much easier time getting the words out, she could say more and more words without having to stop to

take a breath, and she was generally becoming more talkative and interactive. Early this fall, I overheard her have a 20-minute conversation with a peer. I was absolutely amazed – that had never happened in her whole life! I absolutely love what Speak is doing for Eliza — when I hear her talk at regular speed and fluency, my heart practically sings. It has been almost miraculous — I doubt I would have believed the difference it has made if I hadn't seen it for myself.

Colleen, MD

* * *

A5

[Parents' testimonials continued as one scrolls down the page]

THIS TO ME WAS MIRACULOUS AND ASTOUNDING

I learned about Speak from an online support group made up of parents facing similar issues as my son; I wrote to the parents in the group in late December out of concern regarding the lack of speech development in my 3.5 year old son. . . . After upping the dosage to 4 capsules a day for the 3 year old and two a day for the 1 year old, in the last few days I have seen an increase in attempts at meaningful expressive language in the boys I realized that there was something to this product when for the first time this past weekend, my 3.5 year old came up to me, looked me in the face and said, "I want something to eat" . . . later on the same day he came to the kitchen and said "I want something to drink"! [sic] This to me was miraculous and astounding . . . given we have been trying to get him to point at what he wants or just say "juice" or "cookie" just to indicate what he wants (we have been modeling sentences and or [sic] sign language to make requests for food for over a year.]" . . .

Warmest regards,

Faith

* * *

I AM THRILLED WITH YOUR PRODUCT

. . . Thank you for making a superb product when you made Speak. It is so nice as a mother of a special needs child to trust in a company to deliver such exceptional products. My son takes it every day and never complains. I know the importance of Omega's [sic] and vitamin E, and I am thrilled with your product.

Thank you once again for all you do for our children.

Highest regards,
Kristin Selby Gonzalez
Autism Hope Alliance, Chairman

* * *

A6

[Parents' testimonials continued as one scrolls down the page]

SPEAK VITAMINS HAVE HELPED MY LITTLE BOY TALK

. . . Speak vitamins are essential nutrients for my son. Speak vitamins have made my little boy talk. He is five years old and has not spoken until I began giving him the vitamins in November of this year. It took two days of giving them to him to hear him speak. I don't mean just a random word every now and then,[sic] I mean he now speaks in complete sentences. He carries a conversation with me. We have sat thru [sic] dinner for five years with nothing but silence from our child, and then he just started talking two days after starting your vitamins. . . . It gave me the best Christmas present in the entire world — hearing my little boy talk.

Laura B.

* * *

A7-8

[Parents' testimonials continued as you scroll down the page]

INCREASED SELF-AWARENESS AND DEEPENING OF COMMUNICATION SKILLS

My son is 5 1/2 and was diagnosed in fall 2009. At that point, he had retreated into complete echolalia as his only means of communication. . . . We tried Speak the morning of February 15. In TWO HOURS, while we were playing he looked me in the eye, initiated a conversation -- "Look mom!," and had a non-echolaliac conversation. (Now at this point, he no longer just repeated what others said, but he did repeat himself multiple times)[.] Each new sentence built on the last. . . .

Becky, Portland

* * *

A8

UNPROMPTED SPEECH

I received samples at the Autism One Conference. We just went to 2 capsules after a week and we are thrilled. We lost any little speech our son had about 2 years ago. He is now 9. We upped the cod liver oil we were using as well as TMG but got whispers at best ~ infrequently. We now have some speech again with little prompting and his receptive language is stellar!!! (insert big grin here)
.....

Heather M.

* * *

A9

[Press release, excerpts, in “Media/Press” section]

03/19/2013 – KRISTIN’S KORNER BLOG: THE VITAMIN E OMEGA-3 CONNECTION

* * *

[page 2 of 3, excerpts]

In fact, many of the symptoms of vitamin E deficiency mirror those of verbal apraxia including speech production problems. . . . Resolution of the Vitamin E deficiency has been shown in hundreds of cases to relieve these conditions. . . .

* * *

The improvements responders show to higher doses of omega 3 and vitamin E typically include improved speech (new sounds, words, improved narrative,

more age-appropriate speech). . . .

* * *

A10

[May 15, 2012 Newsletter, excerpts, in “Community Resources” section]

Introducing New Smooth Travel Packs

Same delicious taste . . . now great for on the go!

* * *

Travel sized and ready for life on the go, they’re the easiest way to make sure your child gets every dose of the important nutrients needed for healthy speech development. . . .

* * *

B. Twitter account, @nl_speak, January 7, 2014 (excerpts attached as Exhibit

B1-B3]

B1

[May 3, 2011 tweet]

Clinical evidence and hundreds of parental reports indicate this special blend of #nutrients provides targeted benefits [URL]

B2

[April 15, 2011 tweet]

#omega & #vitaminE #speechdevelopment formula provides ratio of nutrients needed for normal&healthy speech&coordination [URL]

B3

[April 14, 2011 tweet]

#omega3 that actually help with #apraxia and #autism

www.SpeechNutrients.com Order your supply today!

C. Facebook page, “Speak” account, January 7, 2014, excerpts (attached as

Exhibit C):

[May 21, 2013 Facebook post]

Tuesday tip: We’ve had some good questions regarding the storage of our speak Smooth. . . . Read more about speak smooth at: [URL]

[depiction of Speak package on the right, omitted]

SpeechNutrients speak™
www.speechnutrients.com

speak™ Smooth is a patented nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance.

D. Rotating-banner ad appearing on 2013 AutismOne Conference website, May 9, 2013, excerpts (attached as Exhibit D1-D4):

[www.autismone.org/Conference-Sponsors-Autismone-Conference-2013]

D1

nourishlife
SpeechNutrients

speak™

PROVEN
Omega-3, Vitamin E
Formulation for
Speech Development

D2

* * *

Only formulation that provides precise doses and ratios of 7 key ingredients

* * *

D3

TARGETED BENEFITS:

- Nutritional support of verbal/motor skills

* * *

D4

[depiction of speak packages, affixed to the lower right]

**AUTISM
APPROVED**

E. Email, excerpts (attached as Exhibit E)

nourishlife

SpeechNutrients speak

Make plans now to join this must-attend event . . .

The Medical Academy of Pediatric Special Needs
Spectrum Standard of Care Conference 2012
March 2-4 in Las Vegas, Nevada

* * *

SpeechNutrients is proud to be part of this groundbreaking event where you can learn more about speak™, our patented nutritional formula that was developed to support normal and healthy speech development and maintenance.

* * *

F. Postcard, excerpts, distributed to conference attendees, April 2011 (attached as Exhibit F)

We enjoyed meeting you at Autism Research Institute Conference in Atlanta.

Thank you for stopping by our booth and learning more about the benefits of omega-3 and vitamin E supplementation.

* * *

Our patented speak™ formulation contains the precise dose and ratio of these nutrients to support healthy speech and coordination development.

* * *

G. Consumer Brochure, excerpts (attached as Exhibit G)

nourish**life**
SpeechNutrients **speak**

**Ask your
Practitioner how the
SpeechNutrients
formulation can
help your child**

SpeechNutrients speak™ is a patented nutritional formula developed by a pediatrician to support healthy speech development and coordination. Join the 4,000+ speak families who have experienced targeted benefits including:

- Nutritional support of verbal and motor skills . . .

* * *

H. Consumer Brochure, excerpts (attached as Exhibit H)

[page 1 of 2, excerpts]

* * *

[outlined text, located, with a depiction, at left-center]

A study published in *Alternative Therapies in Health and Medicine*¹ reported data on 187 children supplementing with an omega-3 and vitamin E combination (as found in the speak formulation). 97% of the children showed dramatic improvements in speech, behavior, sensory issues, imitation, coordination, and eye contact. Supplementation with this omega-3, vitamin E combination is believed to reduce inflammation and oxidative stress.⁺

To read the study in its entirety, go to apraxiaresearch.com

[stand-alone text, located at right-hand-side, top]

What is SpeechNutrients speak?

SpeechNutrients speak™ is a patented formulation that provides a precise dose & ratio of the important nutrients needed for normal and healthy speech and coordination development. . . .

* * *

The nutrients in SpeechNutrients speak™ provide targeted benefits, including but not limited to:⁺

- Nutritional support of verbal and motor skills . . .

* * *

[parent testimonial, located at left-hand-side, bottom corner]

The main difference is that she is trying and willing to put three words together on her own with no prompting. . . .

Tracey in Illinois

* * *

[parent testimonial, located at right-hand side, center]

We were really amazed when Ben started singing along with a song on the radio. . . . and he was singing 3+ word phrases, not just one word here & there. When I pick up Ben from school now, he is talking a lot & consistently answers questions. His teachers report he answers them consistently as well, even with open-ended questions if they aren't too far in the future.

Dorianne in California

* * *

[page 2 of 2, excerpts]

Why is this particular formulation effective?

* * *

Research has shown that these nutrients play an important role in speech and coordination development, and thousands of children have experienced positive outcomes while taking these nutrients. Due to potential issues with malabsorption, some children may be deficient in Vitamin E and at the same time may not absorb it well. In fact, many of the symptoms associated with speech issues mirror vitamin E deficiency.

* * *

[parent testimonial, located at left-hand-side, bottom]

We have seen significant benefits in his speech including increase in vocalizations, babbling and ability to imitate speech sounds more readily. We have been on other fish oil supplements in the past and there is no comparison to the differences that we see with speak™. . . .

Lisa, VA

[parent testimonial, located in center, bottom]

John has been taking 3 speak™ capsules a day for a few weeks and we are just upping him to four capsules a day. Not only is he speaking more, there is less of

him repeating what he hears/sees. . . .

Agnes L., CA

* * *

I. Speak Fact Card, excerpts (attached as Exhibit I)

[page 1 of 2, excerpts]

nourishlife

SpeechNutrients speak™ Dosage Information

[depiction of 12-week dosage recommendation chart]

* * *

- Begin with one speak™ capsule daily (given with food) and increase slowly.
- Toddlers and smaller children may see the most benefits with 2 to 4 capsules per day.
- Older and larger children may see the most benefits with 4 to 6 capsules per day.
- Consider increasing dosage until no additional benefits are noted, at that point revert back to the prior weeks' [sic] dosage. Increased benefits are often noted at higher doses.
- Administering speak for a minimum of 4 months may be required to determine potential benefits

* * *

Why is speak unique™?

Omega-3 is found in many forms and combinations including high EFA, high EPA, and omega-3, 6, 9. While these may be beneficial for the general population, they do not contain the additional nutrients in doses and ratios necessary for the unique population of children concerned with speech and coordination. . . .

* * *

[page 2 of 2, excerpts]

nourishlife

SpeechNutrients speak™ Nutrient Information

* * *

[in-between two illustrations containing ingredient information]

* * *

Are there any side effects?

Possible side effects are typically associated with omega-3 and vitamin E supplements (not unique to speak™). Moodiness, irritability, and emotional outbursts are sometimes reported in children during the first few days/weeks of omega-3 supplementation; however, this usually comes with increased babbling, imitation of sounds, and eventually words to sentences. . . .

* * *

J. Consumer FAQs, excerpts (attached as Exhibit J)

[page 1 of 3, excerpts]

nourish**life**
SpeechNutrients

NourishLife Speak Dosage Information / Questions

* * *

[list of questions]

1. How should I begin supplementing with speak?

* * *

If your child is already taking individual omega-3 fish oil and vitamin E supplements:

- First determine the current dosage amount of the active omega-3 (EPA and DHA) and vitamin E (if any) that your child is receiving with the existing supplement Shown below is a chart illustrating the amounts of each ingredient and how 2 [sic] capsules of speak provide the essential equivalent to two capsules of the other supplements plus additional nutrients in speak provide added benefits and nutrient balance, not found in other omega-3 supplements.

5. When should I begin to notice beneficial changes in my child?

Every child is different and responses vary. Occasionally, families report beneficial changes in their children within the first few days of supplementation. Others notice advances in speech and coordination after several weeks. It is not uncommon to supplement for several months before significant progress is made including speech, coordination, and motor planning. . . .

* * *

[page 3 of 3, excerpts]

6. Is speak effective for older children and does it take longer to be effective?

Families have reported positive results in older children. It may take longer to see the benefits in older children, depending on the child’s health status and health history and underlying GI issues and/or allergies

* * *

8. What are some possible side-effects associated with omega-3 and vitamin E supplementation? (*The issues described are typically associated with all omega-3 and vitamin E supplements – not unique to NourishLife speak.*)

* * *

b. Moodiness, irritability, and emotional outbursts are commonly reported in children during the first few days/weeks of omega-3 supplementation; however, this usually comes with increased babbling, imitation of sounds, and eventually words to sentences.

* * *

K. Front and side panel of Speak Softgels (Natural Orange) package.



12. Defendants also have entered into agreements with Google to preferentially display a textual link or “sponsored link” to a website marketing Speak, in response to searches that consumers perform on Google’s search engine about childhood speech and language development. As a result, if consumers entered terms such as “toddler speech problems,” “help my child talk,” “verbal apraxia treatment,” “autism treatment,” “speech delay treatment,” “child speech development,” or “3 year old not talking,” into Google’s search engine, a sponsored link for Speak appears at the top or the right-hand-side of the search results returned, such as Exhibit K. Clicking on one of Defendants’ sponsored links for Speak causes a webpage or “landing page” to appear, such as Exhibit L. These sponsored links and landing pages have contained, among others, the following statements and depictions:

A. Sponsored links, excerpts (attached as Exhibit K1-K3)

K1

[search term: “toddler speech problems,” January 8, 2014]

Healthy Speech for Child – SpeechNutrients speak Supplement
[URL]
Formulated by a Pediatrician

* * *

K2

[search term: “help my child talk,” December 20, 2013]

Speech Support? - Pediatrician Developed Formulation

[URL]

Try speak TM Starter Kit, Best Value!

* * *

K3

[search term: “verbal apraxia treatment,” May 5, 2013]

Speech Nutrition Support - SpeechNutrients.com

[URL]

Formulation from Childrens [sic] Hospital Blend of 7 Nutrients for **Speech**

* * *

B. Landing page displayed upon clicking sponsored link contained in Ex. K1,
excerpts (attached as Exhibit L)

* * *

Speak TM is changing lives.

HEALTHY SPEECH DEVELOPMENT

PATENTED HYPOALLERGENIC, PEDIATRIATION FORMULATED

Mounting clinical evidence and hundreds of parental reports indicate this special blend of nutrients provided targeted benefits including:⁺

- Nutrition support of verbal and motor skills

* * *

SpeechNutrients speak TM is a patented formula developed by a pediatrician to support normal and healthy speech development and maintenance. Thousands

of parents like you have tried speak™ and have been astonished at the results.

* * *

[Parent testimonials continued as one scrolls down the page]

[Image of mother observing daughter reading, and to the right:]

That formula has done wonders for her! Her speech is within the normal range and the Vitamin E greatly helped. It's the formula we need in 2 capsules instead of 6.

-- *Katie M., New Jersey*

* * *

[Image of child hugging a smiling mother, and to the right:]

I believe she is speaking in more complex sentences and she is less gittery [sic], more focused. We are very impressed with her conversational speech and she is making progress.

-- *Ali R., West Virginia*

* * *

13. Defendants also have promoted Speak through the website apraxiaresearch.com ("Apraxia Research website"), to which the SpeechNutrients website linked. The Apraxia Research website purported to provide research and other scientific information relating to the treatment of apraxia. In fact, the website promoted the health benefits of an "omega 3/vitamin E speech supplement" for children and reported "Parental Feedback," which consisted of testimonials from parents who gave their children a "patented omega3/vitamin E speech supplement." At the time Defendants disseminated the Apraxia Research website, NourishLife was the only seller of an Omega-3 fatty acid and Vitamin E supplement purported to be a patented formula to develop speech in children. The Apraxia Research website also solicited participation in an "ongoing Study Group," which Defendants controlled and conducted, to

investigate an “omega 3/vitamin E speech supplement.” Parents who applied to participate in this study group received a free product trial for Defendants’ Speak and, if not accepted into the study group, coupons to purchase Speak at a discounted price. The Apraxia Research website did not disclose that Defendant NourishLife was the owner, developer, and operator of the website. The website, excerpts of which are attached as Exhibit M, included, among others, the following statements and depictions:

A. www.apraxiaresearch.com, July 2, 2013, excerpts (attached as Exhibit M1-M3).

M1

[Home page of Apraxia Research website]

Progressing information and research in the treatment of Apraxia

Welcome to ApraxiaResearch.com. This site provides resources and information for parents and professionals regarding past and present research developments for the treatment of verbal, oral and motor Apraxia. In cooperation with researchers, ApraxiaResearch is leading an initiative seeking to understand how certain nutrients play a key role in reducing inflammation and oxidation which appears to be a formidable issue in individuals with this challenging speech disorder.

* * *

Participate in an ongoing Study Group

ApraxiaResearch is providing the opportunity for a select group of families to receive an omega-3/vitamin E speech supplement complimentary for a 2 month

study period. . . .

* * *

Clinical Research

Recently published research regarding omega-3 and vitamin E supplementation and the role it plays in Verbal Apraxia.

* * *

M2

[Testimonials listed in “Parental Feedback” Section]

I started using a patented omega-3/vitamin E speech supplement three weeks ago for my 5 year old son, adopted by me at 2 years of age, who had always talked in mumbled, muffled voice. . . . On his seventh day, taking 2 capsules a day, [he] began talking more clearly and in full sentences. On his 8th day I began giving him 3 capsules a day. On his 14th day I met with his school teacher as well as his speech teacher. Both wanted to know what we had done to improve [his] speech so quickly and dramatically . . .

-- Kathy L, TN

* * *

My son’s private speech therapist says that he has made 3-4X the progress [sic] than he normally does in the same time period! We are seeing (and hearing) more imitation and initiation of speech, plus he is putting together 3-4 syllables on his own. Before the supplement, he struggled to say 1-2 syllable words.

-- Jeanne, IL

* * *

The omega-3/vitamin E nutrients are helping my son and I am very grateful. He was born at 27weeks [sic] gestation and weighed only 1.4 pounds. He is now 4 with significant speech delays and sensory issues. Since I have been giving him the supplements, he is talking much more and able to process his thoughts enough to talk in more complex sentences and thoughts. I stopped giving it to him for a week and noticed that his communication diminished. . . .

-- Samantha, OK

* * *

. . . [Our boy] has made INCREDIBLE progress. We have been blown away!

The patented omega 3/vitamin E speech supplement is miraculous!! He has gotten the best reports ever from school. It is impossible to not see the difference in him. . . . The best way to explain it is that he is now like any other 3 year old, only with a significant speech delay and some low tone. . . . The changes are not subtle at all. We took [him] to a big Chanukah party at our country club where in previous years he would just shut down, this year he participated, sat nicely, and was talking! . . .

-- Melissa G . . . , NJ

* * *

M3

[Web page displayed upon clicking box entitled “New Study Published!” or “Clinical Research” tabs on home page (*see* Exhibit M1)]

* * *

Breakthrough Study on Verbal Apraxia

The study Syndrome of Allergy, Apraxia, and Malabsorbtion: Characterization of a Neurodevelopmental Phenotype that Responds to Omega 3 and Vitamin E Supplementation published in the July/August 2009 journal of Alternative Therapies in Health and Medicine describes the improvements noted in 97% of participants while taking a nutritional formulation comprised of omega-3 and vitamin E.

The study identifies the symptoms of vitamin E deficiency as mirroring those of Apraxia and the concurrent need for higher doses of vitamin E in addition to omega-3.

* * *

M4

[Web page displayed upon clicking the tab, on left-hand side, labelled “Research Publications” (*see* Exhibit M1)]

* * *

One of ApraxiaResearch's ongoing goals is the dissemination of information on Apraxia and related disorders in children. We hope that these research publications, articles and study findings will help you in your quest.

* * *

14. Through the Apraxia Research website and the SpeechNutrients website, as well as other means, Defendants recruited parents to participate in a product trial for Speak. Parents who were accepted to participate received a free, two -to-three- month supply of Speak, in exchange for reporting on their child's experience with the product. These complimentary products retailed in the amount of approximately \$143 and \$215, depending on whether the parent received a two-month or three-month supply. In many instances, Defendants obtained testimonials from these parents, which subsequently have appeared in Defendants' advertisements and promotional materials for Speak products, including the Apraxia Research website, SpeechNutrients website, consumer product brochures, and search advertising. *See* Exhibits A4, A6-8, H, L, and M2. Such advertisements and promotional materials containing these testimonials have not disclosed that parents endorsing Speak products received complimentary products from Defendants.

15. The SpeechNutrients website also includes a testimonial endorsing Speak products from Kristin Selby Gonzalez, who is identified as the Chairman of the non-profit organization, Autism Hope Alliance. *See* Exhibit A5. Ms. Gonzalez also authored "Kristin's Korner Blog: The Vitamin E Omega-3 Connection," which appears on the SpeechNutrients website, among other places. *See* Exhibit A9. Proposed Defendants have provided complementary Speak products to Ms. Gonzalez, on an ongoing-basis, since at least

February, 2012. Advertisements and promotional materials for Speak products containing Ms. Gonzalez's product endorsement and her blog discussion on the benefits of Vitamin E and Omega-3 supplementation have not disclosed Ms. Gonzalez's receipt of free products from Defendants.

DEFENDANTS' VIOLATIONS OF THE FTC ACT

16. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce.

17. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Defendants' Speak is either a "food" or "drug" as "food" and "drug" are defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c).

COUNT I

False or Unsubstantiated Efficacy Claims

18. Through the means described in Paragraphs 11 through 13, Defendants have represented, expressly or by implication, that:

A. Regular use of Speak causes, or assists in causing, children to develop and maintain normal, healthy speech and language capacity, including in those children who have apraxia and autism spectrum disorders, among other developmental conditions;

B. Speak treats or mitigates verbal apraxia and communication and behavioral deficits in children who have autism spectrum disorders, among other developmental conditions; and

C. Children who use Speak, including children who have apraxia and autism spectrum disorders, among other developmental conditions, are likely to obtain the rapid and significant speech, language, and other behavioral improvements reported by parent endorsers who appear in Defendants' advertisements;

19. The representations set forth in Paragraph 18 were false and misleading, or were not substantiated at the time the representations were made.

20. Therefore, the making of the representation as set forth in Paragraph 18 of this Complaint constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT II

False Proof Claim

21. Through the means described in Paragraphs 11 through 13, Defendants have represented, expressly or by implication, that Speak is clinically proven to develop and maintain normal, healthy speech and language capacity in children, including children who have apraxia and autism spectrum disorders, among other developmental conditions.

22. The representation set forth in Paragraph 21 is false.

23. Therefore, the making of the representations as set forth in Paragraph 21 of this Complaint constitutes a deceptive act or practice and the making of false

advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT III

Means and Instrumentalities

24. Defendants have provided advertisements and promotional materials to third-party distributors and resellers for use in the marketing and sale of Speak, including Exhibits H through J.

25. Through the means described in Paragraph 24, Defendants have provided means and instrumentalities to these third-party distributors and resellers in furtherance of the deceptive and misleading acts or practices alleged in Paragraphs 18 through 23 of this Complaint.

COUNT IV

Misrepresentations about the Apraxia Research Website

26. Through the means described in Paragraph 13, Defendants have represented, expressly or by implication, that the Apraxia Research website is an independent, objective resource for research and other scientific information relating to the treatment of apraxia and Omega-3 fatty acid and Vitamin E supplementation.

27. In truth and in fact, the Apraxia Research Website is not an independent, objective resource for research and other scientific information relating to the treatment of apraxia and Omega-3 fatty acid and Vitamin E supplementation.

28. Therefore, the making of the representation as set forth in Paragraph 26 of this Complaint constitutes a deceptive act or practice in or affecting commerce, in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT V

Failure to Disclose Material Connections

29. Through the means described in Paragraph 13, Defendants have represented, expressly or by implication, that the Apraxia Research website provides research and other information relating to the treatment of apraxia and Omega-3 fatty acid and Vitamin E supplementation.

30. In numerous instances in which Defendants have made the representation set forth in Paragraph 29 of this Complaint, Defendants have failed to disclose, or disclose adequately, that Defendants owned, developed, and operated the Apraxia Research website.

31. Through the means described in Paragraphs 11 through 13, Defendants have represented, expressly or by implication, that parent and other endorsers appearing in advertising for Speak are satisfied users of Speak.

32. In numerous instances in which Defendants have made the representations set forth in Paragraph 31 of this Complaint, Defendants have failed to disclose, or disclose adequately, that certain of the parent and other endorsers appearing in their advertising were compensated in connection with their endorsement, including through the means described in Paragraphs 14 and 15.

33. The information described in Paragraphs 30 and 32 would be material to consumers in deciding whether to purchase and use Speak.

34. Defendants' failure to disclose the material information described in Paragraphs 30 and 32, above, constitutes a deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. §§ 45(a).

CONSUMER INJURY

35. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

36. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Federal Trade Commission, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act by Defendants;

B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and

C. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

JONATHAN NUECHTERLEIN
General Counsel

Dated: January 7, 2015

Laura M. Sullivan
Paul B. Spelman

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, NW
Washington, D.C. 20580
Maildrop CC-10528
Tel.: 202-326-3327, -2487
Fax: 202-326-3529
lsullivan@ftc.gov; pspelman@ftc.gov

/s/ Matthew H. Wernz
Matthew H. Wernz (Illinois Bar No. 6294061)
Federal Trade Commission
55 W. Monroe Street, Suite 1825
Chicago, Illinois 60603
Tel.: 312-960-5596
Fax: 312-960-5600
Email: mwernz@ftc.gov

Attorneys for Plaintiff
FEDERAL TRADE COMMISSION