



March 27, 2013

VIA FEDEX

Barbara O. Schneeman, Ph.D.
Director, Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
Rockville, MD 20740

Re: Improper Marketing and Other Issues Regarding Supplement
SpeechNutrients speak™ Marketed by NourishLife

Dear Dr. Schneeman:

It is estimated that as many as six million children in the United States suffer from speech delays.¹ Because such delays can have a devastating impact on personal, social, emotional, academic and, later on, vocational life,² it is not surprising that parents are typically desperate to help their children overcome such speech difficulties. This is where NourishLife, LLC and its subdivision, SpeechNutrients (collectively "NourishLife") come in.

NourishLife markets "a patented nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance." The supplement is called SpeechNutrients speak™ ("Speak"), and contains vitamin E and K, omega-6, and "pharmaceutical grade" omega-3. According to some of the testimonials on the NourishLife website, Speak can improve speech within hours of the child taking the first dose.

Unfortunately, as pertains to the U.S. Food and Drug Administration (FDA), there are three primary problems with Speak.

- First, the supplement is being marketed as a treatment for childhood speech delays, such as apraxia,³ without proper approval by the FDA, and without proper substantiation.

- Second, Speak's labeling contains false and misleading claims, and does not have adequate instructions for use or warnings.
- Third, the amount of vitamin E contained in Speak far exceeds the tolerable upper intake level set by the Food and Nutrition Board, and may be hazardous to the health of children.

In short, NourishLife is not only marketing Speak as a treatment for childhood speech delays, but using deceptive labeling tactics to sell a potentially harmful supplement to children with disabilities. Truth in Advertising, Inc. ("TINA")⁴ brought this matter to the company's attention on March 19, 2013, requesting that it correct the deceptive advertising of its product and alert its Speak customers of the issues by March 26, 2013. The company did not comply with TINA's requests. Thus, TINA now brings this matter to the attention of the FDA in the hopes that it will act in the best interests of children with speech delays and their parents, and put an end to NourishLife's misleading and deceptive practices.

Below, TINA sets forth in detail NourishLife's treatment claims, as well as the labeling falsehoods and omissions it uses to market its supplement Speak, and the health concerns associated with taking the supplement. TINA has also filed a complaint with the Federal Trade Commission (FTC), as well as Illinois Attorney General Lisa Madigan.

I. What is Speak?

Speak is marketed and sold by NourishLife, an Illinois corporation founded by a Chicago businessman and "natural entrepreneur," Mark Nottoli.⁵

The supplement contains omega-3 fatty acids (in the form of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)), vitamin E (in the form of d-alpha tocopherol and gamma tocopherol), vitamin K1 and K2, and omega- 6 (in the form of gamma linolenic acid (GLA)).⁶ According to the Supplement Facts on the product package, two capsules of Speak contain 5,000% of the daily value of vitamin E for children under the age of four, and 1,665% of the daily value of vitamin E for children over the age of four.⁷ NourishLife suggests that, after a short introductory period, parents give their children between two and six capsules of Speak per day.⁸

The supplement, which was originally placed on the market in 2008, is promoted as a treatment for childhood speech delays,⁹ and is primarily targeted at children with apraxia and/or autism.

NourishLife, which reports to have sold thousands of boxes of Speak,¹⁰ primarily promotes and makes claims about the supplement directly through its website, www.speechnutrients.com. The company also promotes the product through, among other mediums, electronic newsletters,¹¹ Google advertisements,¹² its

Facebook page,¹³ its Twitter page,¹⁴ another website owned by the company – ApraxiaResearch.com, and promotional booths at trade shows and conferences.¹⁵

II. NourishLife's Treatment Claims Render Speak an Unapproved Drug Under the Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act ("FDCA") defines "drugs" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."¹⁶ In several places, NourishLife represents, expressly or by implication, that Speak treats childhood speech delays, and more specifically, apraxia.

A. Product packaging

On its product label, NourishLife states:

"The patented omega-3 + vitamin E formulation developed by a pediatrician to support normal and healthy speech development and maintenance. . . . Pharmaceutical Grade Dietary Supplement."¹⁷

The label further states:

"This special blend of nutrients provides targeted benefits including:

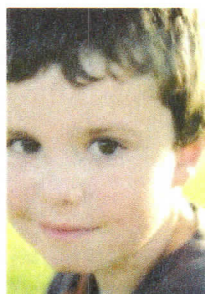
- Nutritional support of verbal and motor skills
- Reduction in oxidative stress
- Promotion of a healthy inflammatory response"¹⁸

B. Website

Similarly, on its website, NourishLife states:

"The only omega-3 and vitamin E speech development formula that provides the precise serving and ratio of the important nutrients needed for normal and healthy speech and coordination."¹⁹

Additionally, NourishLife posts several testimonials on its website that indicate that Speak can treat childhood speech delays.²⁰ Some examples of the testimonials include:



INCREASED SELF-AWARENESS AND DEEPENING OF COMMUNICATION SKILLS

... We tried Speak the morning of February 15. In TWO HOURS, while we were playing [my son] looked me in the eye, initiated conversation--"Look mom!," and had a non-echolaliac conversation. . . .



ADDED SENTENCE COMPLEXITY

Since beginning the speech nutrients nearly 3 months ago, twice per daily, we have noticed significant progress in our son's speech development (age 5.5). Our family has been exceptionally pleased with his progress since beginning the speech nutrients; we have noticed an added level of complexity to his sentences and length of conversations he is able to carry with us and peers to be more intelligible. . . .



GREAT RESPONSE TO SPEAK

I am very happy to let you know that my son responded very well to Speak. He is copying everything, he is much better in the social area, he is trying to Speak much more, he seems to understand better and he pays more attention to everyone, I am really impressed with the progress in only 1 week. Thank you.²¹

The unmistakable message, after reading the over thirty-five testimonials regarding the effectiveness of Speak posted on the website, is that Speak can significantly improve childhood speech delays, sometimes almost immediately.²²

C. Patent application

The patent application that was filed for the Speak formula with (and ultimately rejected by) the U.S. Patent and Trademark Office indicates that it is "[a] method of treating apraxia and/or autism spectrum disorder."²³

D. Social media sites

On its Facebook page, NourishLife states, among other things, "NourishLife speak™ is a patented nutritional formula developed by a pediatrician to support normal and healthy speech development and maintenance."²⁴ On its Twitter page, NourishLife states, among other things, "#omega3 that actually help with #apraxia and #autism[.] www.SpeechNutrients.com Order your supply today!"²⁵

Based on these statements and claims, Speak meets the FDCA's definition of a "drug."²⁶ Further, because NourishLife has not filed a drug approval application with the FDA for Speak, the company has violated section 505(a) of the FDCA, 21 U.S.C. § 355(a), which requires that all new drugs be approved by the FDA prior to being placed on the market.²⁷

III. NourishLife Lacks Substantiation for its Treatment Claims

Despite making treatment claims and stating that such claims are supported by “mounting clinical evidence,”²⁸ NourishLife’s claims are not supported by any competent and reliable scientific studies.

A. Morris and Agin study

On its website NourishLife touts a study conducted by two physicians, Dr. Claudia Morris and Dr. Marilyn Agin, as the primary support for its claims that Speak treats apraxia. On the Scientific Research page on its website, NourishLife states:

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.²⁹

In this study, *Syndrome of Allergy, Apraxia, and Malabsorption: Characterization of a Neurodevelopmental Phenotype that Responds to Omega 3 and Vitamin E Supplementation*, C. Morris and M. Agin, *Alternative Therapies*, Jul/Aug 2009, Vol. 15, No. 4 (hereinafter “Morris and Agin study”), Drs. Morris and Agin examined 187 children with verbal apraxia between the ages of 2 and 15.³⁰ The children were given varying doses of vitamin E, as well as varying doses and brands of polyunsaturated fatty acids (PUFAs).³¹ The families of the children then shared their experiences with the supplements either by filling out an online questionnaire or by personal communication.

According to the study, 181 families (i.e., 97% of the studied population) reported “dramatic improvements in a number of areas including speech, imitation, coordination, eye contact, behavior, sensory issues, development of pain sensation, and GERD symptoms.”³² Despite these seemingly promising results, the study has limitations, including:

- The study was not a randomized, double-blind, placebo-controlled trial. In fact, the researchers did not use any sort of control group whatsoever to determine whether the perceived improvements were caused by the supplement or by something else, such as the placebo effect;
- The results of the study are based purely on subjective responses by parents;
- The children in the study were given widely varying doses of the supplements under investigation. For example, the doses of vitamin E ranged from 400 International Units (“IU”) to 3000 IU a day;

- The authors of the study admit that many of their conclusions are speculative; that there were major limitations in their report; and that further controlled research is warranted in order to determine the effect of the supplement on children with apraxia;³³
- The study includes very little information about the type of questionnaire used and does not explain the nature of the questions (e.g., multiple-choice, open-ended, check boxes);
- The study is silent with respect to how the questionnaire results were tallied and analyzed, and does not indicate whether the children's histories, such as other interventions used, were recorded or even considered;
- The study does not include any information regarding the length of time (e.g., weeks, months) the children were instructed to take the supplements at issue;
- The study does not include the same ingredients that are contained in the Speak supplement. Specifically, vitamin K, one of the key components of Speak, was not part of the Morris and Agin study.

In short, the Morris and Agin study does not provide any competent and reliable scientific support for NourishLife's claims regarding Speak.

B. Richardson and Montgomery study

NourishLife also lists another study on its website, *The Oxford-Durham Study: A Randomized, Controlled Trial of Dietary Supplementation with Fatty Acids in Children with Developmental Coordination Disorder*, Alexandra J. Richardson, and Paul Montgomery (hereinafter "Richardson and Montgomery" study), to support its claim that Speak treats apraxia.³⁴ However, this study also has its limitations. While this study was a randomized, double-blind, placebo-controlled trial, it did not examine speech delays or the effect of vitamin E or vitamin K. Rather, the Richardson and Montgomery study only examined the effect of omega 3 and omega 6 on children with developmental coordination disorder (DCD), a childhood disorder that leads to poor coordination and clumsiness.

This study concluded that the fatty acid supplementation had no effect on motor skills, but improved reading, spelling, and behavior in children with DCD. The study does not indicate whether fatty acid supplementation has any effect on speech delays, let alone what the effects of a supplement like Speak might have with respect to healthy speech development.

C. “Additional References”

In small print on its “Scientific Research” page, NourishLife lists 38 “additional references” that purportedly support Speak and its claimed benefits.³⁵ However, none of the references cited support the claim that a supplement made up of Omega-3s, vitamin E, vitamin K, and Omega-6 improves speech in children with apraxia. In fact, TINA is not aware of any clinical, double-blind studies that show that a mix of Omega-3, Omega-6, and high doses of vitamin E and vitamin K improve speech in children with apraxia.

IV. NourishLife’s Labeling Renders Speak a Misbranded Drug Under the FDCA

Pursuant to Section 502(a) of the FDCA, a drug is deemed misbranded if its labeling is false or misleading.³⁶ Further, pursuant to Section 502(f) of the FDCA, a drug is deemed misbranded unless its labeling bears adequate directions for use, and bears

misleading because the FDA has not defined what would constitute a pharmaceutical grade fish oil product, and thus the term is meaningless.⁴⁷

B. NourishLife's inadequate directions for use and label warnings

Speak's packaging does not have adequate directions for use or label warnings. First, childhood speech delays, such as apraxia, require diagnosis by a healthcare professional.⁴⁸ Thus, adequate directions for use must warn that a layman cannot use the product safely without proper professional diagnosis.⁴⁹ Because Speak's directions for use do not include any such language, the product is misbranded.⁵⁰

Second, as discussed in detail below, there are some significant health and safety concerns associated with giving Speak to children, especially in elevated dosages. Speak's label does not fully warn of these issues, thus rendering Speak a misbranded drug under section 502(f) of the FDCA.⁵¹

V. Health and Safety

A. Vitamin E

i. Amount of vitamin E in Speak

One capsule of Speak contains 250 IU of vitamin E in the form of d-alpha tocopherol and 150 IU of vitamin E in the form of gamma tocopherol.⁵² NourishLife suggests that, after a short introductory period, parents give their children between two and six capsules of Speak per day, meaning that children taking the supplement are ingesting between 500 IU and 1500 IU of vitamin E in the form of d-alpha tocopherol, and an additional 300 IU to 900 IU of vitamin E in the form of gamma tocopherol on a daily basis.⁵³

The tolerable upper intake level (i.e., the maximum daily intake unlikely to cause adverse health effects) for vitamin E set by the Food and Nutrition Board (FNB) at the Institute of Medicine of The National Academies is 300 IU for children between 1 and 3 years of age, and 450 IU for children between 4 and 8 years of age.⁵⁴

This means that children between the age of one and three taking Speak are exceeding the tolerable upper intake level for d-alpha tocopherol by 66% to 400% (depending on whether they take two, four, or six capsules per day), and children between the age of four and eight are exceeding the tolerable upper intake level for d-alpha tocopherol by 11% to 233%. Further, by NourishLife's own calculations, children under the age of four taking Speak are receiving between 5,000% and 15,000% of the daily value of d-alpha tocopherol, while children over the age of four are receiving between 1,665% and 4,995% of the daily value.⁵⁵

Of note, the FNB's vitamin E intake levels are for d-alpha tocopherol alone. They do not include the appropriate intake levels for gamma-tocopherol.⁵⁶

ii. Dangers associated with high doses of vitamin E

These extremely high doses of vitamin E are alarming. The NIH reports that high doses of alpha-tocopherol supplements can cause hemorrhaging, as the supplement is a blood thinner.⁵⁷ The NIH also cites to two clinical trials that have found an increased risk of hemorrhagic stroke in participants taking alpha-tocopherol.⁵⁸

In another study, researchers found that healthy men who took 400 IU of vitamin E per day (which is 400 IU *less* than the *minimum* amount of vitamin E children on Speak are taking) had a significantly increased risk of prostate cancer.⁵⁹ In yet another study, researchers at Johns Hopkins University found that use of high-dose vitamin E supplements, again, in excess of 400 IU, is associated with a higher overall risk of dying.⁶⁰

In an interview with CBS News, Edgar R. Miller III, MD, PhD, one of the lead researchers of the Johns Hopkins study, explained that there are several theories regarding why vitamin E increases the risk of death.⁶¹ One theory is that vitamin E is a blood thinner and increases the risk of bleeding, which, in turn, increases the risk of stroke. Another theory is that when vitamin E is given in high doses, the vitamin stops working like an antioxidant (which removes harmful molecules in the body) and instead becomes a pro-oxidant, promoting the production of harmful molecules. A third theory suggests that high doses of vitamin E “wipe out other antioxidants, which disrupts the body’s natural antioxidant protection system.”⁶² Dr. Miller then stated that, even without a clear explanation of how vitamin E may increase mortality, people should not take the vitamin.⁶³

Based on this research, there can be no question that there are health concerns associated with giving children between 800 and 2400 IU of vitamin E per day.⁶⁴ As for the other components of Speak – vitamin K and omega-3 and 6 – see endnotes 57 and 65.

B. Adverse effects reported by NourishLife and by parents of children taking Speak

Given the elevated doses of vitamins in Speak,⁶⁵ it is not surprising that some parents have reported that their children experienced adverse effects after taking the Speak supplement. One mother reported that her 11-year-old son regressed after taking Speak, while another mother reported that her 3-year-old daughter experienced seizure-like behavior for the first time after taking Speak.⁶⁶ Further, according to NourishLife, healthy children taking Speak can experience diarrhea, and moodiness, irritability, and emotional outbursts.⁶⁷ In short, there can be no question that Speak may pose a health risk to children.

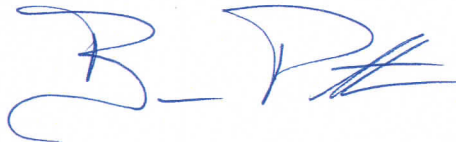
VI. Conclusion

For the reasons stated in this complaint, TINA urges the FDA to move quickly in order to halt NourishLife's false and misleading claims regarding Speak. TINA further requests that the FDA use its seizure authority under § 304(a)(1)(B) of the FDCA, 21 U.S.C. §334(a)(1)(B) to immediately remove existing stockpiles of Speak from the marketplace. Such measures are not only necessary to protect consumers from deception, but are a public health necessity.

Sincerely,



Laura Smith, Esq.
Legal Director
Truth in Advertising, Inc.



Bonnie Patten, Esq.
Executive Director
Truth in Advertising, Inc.

¹ *Evaluation and Management of the Child with Speech Delay*, Alexander K.C. Leung, M.B.B.S., June 1, 1999, American Family Physician, available at <http://www.aafp.org/afp/1999/0601/p3121.html> (hereinafter "AFP article") (estimating that between 3 and 10 percent of children have speech delays) (Exhibit 1; *Speech Delay*, available at <http://www.keepkidshealthy.com/welcome/conditions/speechdelay.html> (stating that about 5-10% of children have a developmental disability that causes a delay in their speech and language development) (Exhibit 2); Central Intelligence Agency World Factbook, available at <https://www.cia.gov/library/publications/the-world-factbook/geos/us.html#People> (indicating that the United States population of children under the age of 15 is 62,889,723) (Exhibit 3).

² AFP article (Ex. 1); *Speech Delay in Kids Linked to Later Emotional Problems*, Denise Mann, WebMD Health News, June 28, 2010, available at <http://www.medicinenet.com/script/main/art.asp?articlekey=117624> (Exhibit 4).

³ Verbal apraxia, or apraxia of speech, is a neurological condition involving difficulty coordinating mouth and speech movements.

⁴ TINA is a nonprofit consumer advocacy organization dedicated to empowering consumers to protect themselves against deceptive advertising.

⁵ <http://www.speechnutrients.com/about/key-leadership/> (Exhibit 5).

⁶ <http://www.speechnutrients.com/products/speak/>, under the "Supplement Facts and Dosage" tab (Exhibit 6).

⁷ These daily value percentages pertain only to the d-alpha tocopherol form of vitamin E. See Photograph of Speak product package – Supplement Facts (Exhibit 7). It does not pertain to the gamma tocopherol levels in Speak. The Food and Nutrition Board (FNB) at the Institute of Medicine of the National Academies has not set intake limits and dosages for this form of vitamin E.

⁸ Speak Fact Sheet (Exhibit 8); <http://www.speechnutrients.com/products/speak/>, under the "Frequently Asked Questions" tab (Exhibit 9). In the "Frequently Asked Questions" section of its website, NourishLife suggests consulting a healthcare provider before administering more than four capsules of Speak per day to children, and before administering Speak to children who have certain health issues, such as cerebral palsy, autism, neurological disorders, developmental regression, seizures, or sleep apnea. *Id.*

⁹ It is important to note that identifying the root of a speech delay can be complicated as there are many different causes of this disability, including:

- Neurological disorders, such as autism and apraxia;
- Neurological injuries, such as cerebral palsy (a movement and posture disorder caused by abnormal development of, or damage to, parts of the brain), and receptive and expressive aphasia (loss of the ability to understand and express speech, caused by brain damage);
- Structural/anatomical problems, such as a cleft lip or palate, or vocal chord abnormalities;
- Intellectual disability (i.e., mental retardation);
- Environmental psychosocial deprivation, such as poverty, abuse, neglect, and malnutrition;
- Hearing impairments;
- Developmental/maturation delays;
- Learning disabilities; and
- Selective mutism.

AFP article (Ex. 1); *Speech and Language Delay and Disorder*, University of Michigan Health System, available at <http://www.med.umich.edu/yourchild/topics/speech.htm> (Exhibit 10).

¹⁰ <http://www.speechnutrients.com/products/speak-starter-kit/> (Exhibit 11).

¹¹ NourishLife's February 26, 2013 electronic newsletter (Exhibit 12).

¹² Google advertisements for Speak (Exhibit 13).

¹³ SpeechNutrients' Facebook page (<http://www.facebook.com/speech.nutrients>) (Exhibit 14).

¹⁴ SpeechNutrients' Twitter page (http://twitter.com/#!/nl_speak) (Exhibit 15).

¹⁵ Photograph of Speak trade show booth display (Exhibit 16).

¹⁶ Section 201(g)(B) of the FDCA, 21 U.S.C. § 321(g)(B).

¹⁷ Photograph of Speak product package – front (Exhibit 17).

¹⁸ Photograph of Speak product package – back (Exhibit 18). This same statement also appears on NourishLife's website. See <http://www.speechnutrients.com/> (Exhibit 19).

¹⁹ <http://www.speechnutrients.com/products/speak/> (Exhibit 20).

²⁰ <http://www.speechnutrients.com/community/testimonials/> (Exhibit 21).

²¹ *Id.*

²² In addition, the majority of the testimonials on NourishLife's website are accompanied by beautiful photographs of what appears to be the child of the parent who sent in the testimonial. However, all but one of the photographs that accompany the testimonials regarding the effectiveness of Speak are fakes – professional photographs that are bought and sold for commercial purposes. Specifically, twenty-three images on the testimonial page also appear on www.istock.com, a large database of stock images. See screenshots showing comparison of testimonial images and iStock images (Exhibit 22).

²³ Patent application filed with U.S. Patent and Trademark Office (Exhibit 23); see also Patent Application Amendment (Exhibit 24), which edits the prior treatment language and now states that the Speak formula "is suitable for treating an autism spectrum disorder and/or apraxia."

²⁴ SpeechNutrients' Facebook page (Ex. 14).

²⁵ SpeechNutrients' Twitter page (Ex. 15).

²⁶ See Section 201(g)(B) of the FDCA, 21 U.S.C. § 321(g)(B).

²⁷ "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." 21 U.S.C. § 355(a).

²⁸ <http://www.speechnutrients.com/> (Ex. 19).

²⁹ <http://www.speechnutrients.com/research/> (Exhibit 25).

³⁰ Morris and Agin study (Exhibit 26).

³¹ Omega-3s are a type of PUFA.

³² Morris and Agin study (Ex. 26), at 36.

³³ "Many of our conclusions are speculative in the absence of controlled clinic trials. A better understanding of the underlying mechanisms accounting for these benefits is needed, and controlled research in apraxia and autism is warranted. The subjective nature of parental report and varied doses of supplements used are major limitations of this report. Future investigations should use validated and reliable outcome measures to determine the potential benefits of these nutritional interventions." Morris and Agin study (Ex. 26), at 41.

³⁴ Richardson and Montgomery study (Exhibit 27).

³⁵ <http://www.speechnutrients.com/research/> (Ex. 25).

³⁶ Section 502(a) of the FDCA, 21 U.S.C. § 352(a).

³⁷ Section 502(f) of the FDCA, 21 U.S.C. § 352(f).

³⁸ Photograph of Speak product package – front (Ex. 17); Photograph of Speak product package – side (Exhibit 28); *see also, e.g.,* <http://www.speechnutrients.com/> (Ex. 19); <http://www.speechnutrients.com/products/speak/>, (Ex. 20), <http://www.speechnutrients.com/about/about-chrco/> (Exhibit 29).

³⁹ Photograph of Speak product package – side (Ex. 28).

⁴⁰ *See* Photograph of Speak product package – front (Ex. 17).

⁴¹ On ApraxiaResearch.com, a website owned by NourishLife, the company specifically refers to U.S. Patent Application 20080213239 as the patent application that was filed for the formula in Speak. *See* <http://www.apraxiaresearch.com/clinical-research> (Exhibit 30); *see also* whois.net domain registration for ApraxiaResearch.com, available at <http://www.whois.com/whois/apraxiaresearch.com> (Exhibit 31).

⁴² Though Speak contains vitamin K and omega-6 fatty acids, in addition to omega-3 fatty acids and vitamin E, the Speak formula is touted as an omega-3/vitamin E formula, since, according to NourishLife, those are the two active ingredients.

⁴³ Patent application filed with U.S. Patent and Trademark Office (Ex. 23).

⁴⁴ Rejection of Patent Application – Summary (Exhibit 32); Detailed Rejection Statement (Exhibit 33). In April 2012, following the final rejection, the patent application was amended. No official action has yet been taken with respect to the amendment.

⁴⁵ <http://www.speechnutrients.com/products/speak/>, under "Formulation" tab (Exhibit 34).

⁴⁶ Photograph of Speak product package – front (Ex. 17).

⁴⁷ Product Review: *Fish Oil and Omega-3 Fatty Acid Supplements Review (Including Krill, Algae, and Calamari Oil)*, ConsumerLabs.com (Exhibit 35)

⁴⁸ See e.g., *Childhood Apraxia of Speech*, Better Health Channel, available at http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Childhood_apraxia_of_speech?open, (Exhibit 36).

⁴⁹ See e.g., February 1, 2011 FDA Warning Letter No. 2011-NOL-08 to Tennessee Scientific, Inc./Scientific Formulations LLC, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm241970.htm> (Exhibit 37) (“[B]ecause your products are offered for conditions which are not amenable to self diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so a layman can use the products safely for their intended uses. Thus, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1).”)

⁵⁰ *Id.*; see also December 21, 2010 FDA Warning Letter FLA-11-11 to Natural Options USA Corporation, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm241936.htm> (Exhibit 38); December 2, 2010 FDA Warning Letter FLA-11-09 to Nutri Herb Inc., available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm241794.htm> (Exhibit 39); October 15, 2010 FDA Warning Letter FLA-11-05 to Green Earth Health Food Market, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm241933.htm> (Exhibit 40); Section 502(f)(1) of the FDCA, 21 U.S.C. § 352(f)(1).

⁵¹ Section 502(f)(2) of the FDCA, 21 U.S.C. § 352(f)(2).

⁵² <http://www.speechnutrients.com/products/Speak/>, under the “Supplement Facts and Dosage” tab (Ex. 6). Note that NourishLife lists the amount of gamma tocopherol in Speak in terms of milligrams. TINA has converted the milligrams to IU for the sake of consistency and ease of reference.

⁵³ <http://www.speechnutrients.com/products/speak/>, under the “Frequently Asked Questions” tab (Ex. 9); Speak Fact Sheet (Ex. 8).

⁵⁴ NIH Office of Dietary Supplements, Dietary Supplement Fact Sheet: Vitamin E, available at <http://ods.od.nih.gov/factsheets/vitamine/> (Exhibit 41).

⁵⁵ These percentages do not include the additional amount of vitamin E in the form of gamma tocopherol children on Speak are receiving.

⁵⁶ *Id.*

⁵⁷ *Id.* NourishLife confirms this fact by stating that vitamin E acts as a blood thinner, and to thus “exercise caution” and to avoid taking ibuprofen, aspirin, and Coumadin while taking Speak. See www.speechnutrients.com/products/speak/, under the “Frequently Asked Questions” tab (Ex. 9) and the “Supplement Facts and Dosage” tab (Ex. 6). NourishLife also indicates that it added vitamin K to the supplement in order to balance the vitamin E, because vitamin K assists in blood clotting. (Ex. 9).

⁵⁸ *Id.*; *Vitamins E and C in the Prevention of Cardiovascular Disease in Men*, The Physicians’ Health Study II Randomized Controlled Trial, Howard D. Sesso, ScD, MPH, et al., JAMA Nov. 12, 2008, Vol. 300, No. 18 (Exhibit 42); *The Effect of Vitamin E and Beta Carotene on the Incidence of Lung Cancer and Other Cancers in Male Smokers*, The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group, New England Journal of Medicine, Apr. 14, 1994, Vol. 330, No. 15 (Exhibit 43).

⁵⁹ *Vitamin E and the Risk of Prostate Cancer*, The Selenium and Vitamin E Cancer Prevention Trial (SELECT), Eric A. Klein, M.D., et al., JAMA Oct. 12, 2011, Vol. 306, No. 14 (Exhibit 44). The men in this study were given vitamin E in the form of all rac-alpha tocopherol, otherwise known as dl-alpha tocopherol.

⁶⁰ *Meta-Analysis: High-Dosage Vitamin E Supplementation May Increase All-Cause Mortality*, Edgar R. Miller III, MD, PhD, et al., Annals of Internal Medicine, Jan. 4, 2005, Vol. 142, No. 1 (Exhibit 45). Because this study examined several different clinical trials, it is not clear whether all the participants were given the alpha-tocopherol form of vitamin E. Also, a limitation of the study is that a large portion of the participant population was over the age of 60 and had a pre-existing health condition.

⁶¹ *Vitamin E May Shorten Life*, CBS News, available at <http://www.cbsnews.com/stories/2004/11/10/health/webmd/main654887.shtml> (Exhibit 46).

⁶² *Id.*

⁶³ In the study, the researchers noted that “[o]n the basis of [their] study, high-dosage vitamin E supplementation is clearly unjustified.” Miller study (Ex. 45), at 43. They later noted that “any high-dosage vitamin supplements should be discouraged until evidence of efficacy is documented from appropriately designed clinical trials.” *Id.* at 45.

⁶⁴ To date, the studies that have examined the effects of taking vitamin E have all been conducted on adults. (Children are generally not used in clinical studies.) However, the current research on adults suggests that extreme caution should be taken when giving the vitamin to children, a much more vulnerable population.

⁶⁵ In addition to elevated doses of vitamin E, Speak also contains high doses of vitamin K (i.e., 1 mg of vitamin K1 and 150 mcg of vitamin K2 per capsule). These amounts, especially when doubled, quadrupled, and sextupled, are dramatically higher than the daily adequate intake recommendation set by the FNB (i.e., 30 mcg for children ages 1 to 3, and 55 mcg for children ages 4 to 8). See *Vitamin K Fact Sheet, Dosage*, NIH Medline Plus, available at <http://www.nlm.nih.gov/medlineplus/druginfo/natural/983.html#Dosage> (Exhibit 47) (the FNB has not yet established a recommended daily allowance or a tolerable upper limit for vitamin K). According to some sources, high doses of vitamin K may trigger allergic reactions and should not be taken without a doctor’s recommendation. See, e.g., *Vitamin K*, WebMD, available at <http://www.webmd.com/vitamins-and-supplements/lifestyle-guide-11/supplement-guide-vitamin-k> (Exhibit 48).

Further, based on the opinions of some experts regarding proper dosages of omega-3s, Speak contains an elevated dose of fish oil. (Upper limits and intake levels have not yet been established for this supplement.) According to the NIH, high doses of fish oil may reduce the immune system’s activity, thereby reducing the body’s ability to fight infections. High doses can also increase cholesterol levels in some people, and doses exceeding 3 grams (3,000 mg) may prevent blood from clotting. *Fish Oil*, National Institutes of Health, available at <http://www.nlm.nih.gov/medlineplus/druginfo/natural/993.html> (Exhibit 49).

⁶⁶ *Speech experts wary of untested supplement sold as a speech aid for kids with verbal apraxia*, Deborah L. Shelton, Chicago Tribune, Sep. 16, 2010, available at http://articles.chicagotribune.com/2010-09-16/health/ct-met-speech-supplements-20100915_1_dietary-supplements-speech-therapy-vitamin-e-supplements (Exhibit 50).

⁶⁷ <http://www.speechnutrients.com/products/speak/>, under the “Frequently Asked Questions” tab (Ex. 9) and the “Supplement Facts and Dosage” tab (Ex. 6).