Case #5620  (08/08/13)
NourishLife, LLC
SpeechNutrients Speak
Challenger:   National Advertising Division
Product Type: Dietary Supplement
Issues:  Express and Implied Claims
Disposition: Modified/Discontinued

- As a general rule health-related claims must be supported by competent and reliable scientific evidence.

Basis of Inquiry: Advertising claims made by NourishLife, LLC (“NourishLife” or “advertiser”) on product labeling, on its website and in print advertising were reviewed by NAD as part of its regular monitoring program. The following claims served as the basis of this inquiry:

Express Claims:

“Nutritional Support for healthy speech development.”
“Speech Nutrients Speak Smooth is a patented 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
  • Reduction in oxidative stress
  • Promotion of a healthy inflammatory response”

“Pharmaceutical Grade”
See benefits “as soon as the first week.”
“Others notice advances in speech and coordination after several weeks.”
“The combination of omega-3 within vitamin E together had a dramatic impact on these children’s symptoms, not only helping with speech, but also improved eye contact and helping to improve pain sensation.”
“A patented nutritional therapeutic formulation designed for the treatment of apraxia.”

1 The advertiser advised NAD in writing that it had permanently discontinued its anti-inflammatory claims, an action NAD deemed necessary and appropriate.
2 The advertiser advised NAD in writing that it had permanently discontinued its “pharmaceutical grade” claims, an action NAD deemed necessary and appropriate. NAD was concerned that a dietary supplement using the term “pharmaceutical grade” might confuse consumers. See Hepcare, Inc. (Hepzpone SST), Report #4947 NAD/CARU Case Reports (December 2008) (Recommending that the advertiser modify its claim “pharmaceutical grade” to more accurate convey the message that the extract it uses is the same “pharmaceutical grade” extract that is used in the prescription product sold in Japan.)
3 The advertiser advised NAD in writing that it had permanently discontinued this claim, an action NAD deemed necessary and appropriate.
4 The advertiser advised NAD in writing that it had permanently discontinued this claim, an action NAD deemed necessary and appropriate.
5 The advertiser advised NAD in writing that it had permanently discontinued this claim, an action NAD deemed necessary and appropriate.
6 The advertiser advised NAD in writing that it had permanently discontinued this claim, an action NAD deemed necessary and appropriate.
Advertiser’s Position:

NourishLife markets a line of dietary supplement products under the name “Speak”. The Speak products contain concentrated, ultra-purified omega-3 fatty acids in addition to efficacious amounts of two forms of vitamin E, and Vitamin K. The advertiser contended that the Omega-3 ingredient, a polyunsaturated fatty acid ("PUFA"), works synergistically with the antioxidant vitamin E to reduce oxidative stress. Optimal amounts of both d-alpha and gamma tocopherols function as key antioxidants and operate with PUFA’s to support neurological health and provide essential nutrition. Due to the theoretical blood thinning effects of omega-3 and vitamin E, vitamin K (a normal and healthy blood clotting nutrient) is also included. The advertiser advised that it has a strong interest in addressing deficiencies in omega-3 consumption.

The advertiser asked NAD to note that it markets these nutritional supplement products in a pervasively regulated environment and contended that its marketing complies with federal regulations governing the marketing of dietary supplements. NourishLife contended that its claims are statements of nutritional support in compliance with The Dietary Supplement Health and Education Act of 1994 ("DSHEA").  

The advertiser argued that DSHEA provides that dietary supplements are permitted to make “statements of nutritional support” for products if they meet the following conditions:

1. The statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes the general well-being from consumption of a nutrient or dietary ingredient.

2. The manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading; and

3. The statement contains, prominently displayed and in boldface type, the following, “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.”

Nourish Life contends that all of its claims here are statements of nutritional support that comply with the DSHEA. Its advertisements include the required statement that the claims have not been evaluated by the FDA and are fully supported.

As support for its advertising claims, Nourish Life submitted over 50 articles, including several published results of clinical studies, on the ingredients contained in the Speak products. The published clinical studies reviewed the impact of supplementation of ingredients in Speak products.
including polyunsaturated fatty acids, (including docosahexaenoic (“DHA”), eicosapentaenoic acid (“EPA”) and arachidonic acid (“AA”), some studies included supplementation with Vitamin E while others did not. In the studies, subjects were evaluated for improvements for a variety of symptoms, conditions and behavioral problems related to several childhood disorders including autism, attention deficit hyperactivity disorder “ADHD”, verbal apraxia (“VA”), and developmental coordination disorder (“DCD”).

I. Verbal and Motor Skills Claims

A. Verbal Apraxia Study

The advertiser contended that the results of an observational study of children diagnosed with VA, a neurologically based motor planning disorder that results in delayed speech, supported its claims. In this study, conducted by Claudia Morris and Marilyn Agin, (the “Morris/Agin Study”) parents reported improved symptoms after supplementation with Omega-3 fatty acids and vitamin E.\(^8\) The Morris/Agin Study asked parents to respond to a questionnaire on a VA support network website in which they were asked about supplementation with Omega-3 fatty acids and Vitamin E and response to the supplementation.\(^9\) Doses and brands of Omega-3’s varied, however, a majority of families used supplements that contained 280 mg DHA and 695 mg EPA per dose in liquid or capsule form, given with a meal 1 to 3 times daily, the same dosage (and suggesting dosing regimen) in the Speak products. The data were analyzed on 187 children. The parents of 97% of the child participants reported dramatic improvements in a number of areas including speech, imitation, coordination, eye contact, behavior, sensory issues, development of pain sensation and gastroesophageal reflux disease symptoms. After supplementation, improvements were reported in speech, imitation, coordination, eye contact, behavior, sensory issues, and development of pain sensation in children. The study authors concluded, “use of high-dose PUFA and vitamin E in children with a history of VA appeared to lead to rapid clinical improvement of many symptoms of this neurological condition in a large cohort.”

The study authors recommended Omega-3 and vitamin E supplementation as a complementary approach to VA in addition to traditional speech and occupational therapy, noting:

Vitamin E deficiency causes a constellation of symptoms that overlap those of speech apraxia, limb dyspraxia, hypotonia, and sensory integration dysfunction (including abnormalities in proprioception, vestibular sensation, and pain interpretation) that often occur in VA and ASD.” Low bioavailability of vitamin E creates an environment within the cell membrane where PUFAs are vulnerable to lipid peroxidation and early destruction. This can lead to a functional PUFA deficiency and neurological sequelae that may be reversible through supplementation of vitamin E and PUFA. In addition,

\(^8\) Morris, C., Agin, M., Syndrome of Allergy, Apraxia and Malabsorption: Characterization of a Neurodevelopmental Phenotype that Responds to Omega 3 and Vitamin E Supplementation. Alternative Therapies Vol. 15, No. 4 (Jul/Aug 2009).

\(^9\) Families could report their experiences with PUFA and vitamin E supplementation online or through personal communication.
PUFA supplementation increases utilization of vitamin E in the body. These two supplements may have a synergistic effect at higher doses.

The advertiser asked NAD to note that Vitamin E deficiency can cause symptoms that include expressive speech delay, hypotonia, and sensory integration dysfunction, which are similar to symptoms observed in children with apraxia and related disorders. NourishLife provided NAD with research to demonstrate that supplementation with higher doses of Vitamin can maximize reversal of vitamin E deficiency. “Of 39 children with well-documented Vitamin E deficiency who underwent repletional therapy for one to four years, neurologic symptoms were prevented in 29%, stabilized in 28%, and improved in 46% of the patients” and “…correction of the vitamin E deficiency state, without other therapeutic manipulations, leads to reversal and prevention of the neurologic symptom.”

The Morris/Agin study concluded that a subgroup of children with apraxia and related disorders may suffer from a functional Vitamin E and Omega-3 deficiency and may be responsive to nutritional intervention, as well as traditional speech an occupational therapies to improve their long term outcome.

B. Clinical Studies

The advertiser relied upon the results of clinical trials that reviewed supplementation of Omega-3 fatty acids in children with ADHD and Autism Spectrum Disorders (“ASD”) in support of its claims that Speak products “support normal and healthy speech development and maintenance” and provide “nutritional support of verbal and motor skills.” The studies evaluated subjects’ symptoms both before and after supplementation to measure improvement for issues such as attention, conduct, and behavior. The results found improvement in symptoms associated with ADHD and ASD. The Patrick/Salik study, for example, demonstrated “significant increases in language and learning skills” when taking a combination of EPA, DHA, GLA, and vitamin E for 90 days using Assessment of Basic Language and Learning Skills (ABLLS) and concludes, “The results of this study strongly support the benefits of essential fatty acid supplementation on language and learning skills in autism and Asperger’s syndrome.”

11 The VA Study noted that a high percentage of children with VA and Autism Spectrum disorders had evidence of a carnitine deficiency. The study suggested that carnitine can be a clue to metabolic disorders and plays a critical role in fatty acid transport and may contribute to abnormal fatty acid metabolism.
study found “a statistically significant improvement in their autistic behavior according to CARS (Childhood Autism Rating Scale),” including improvement in verbal communication scores.

In addition to the clinical studies on Omega-3 supplementation on symptoms of ADHD and Autism, the advertiser submitted the results of two clinical trials on the impact of Omega-3 supplementation on DCD, a condition which involves impairment of motor functions including difficulties with organizational skills, written language, and behavior. The symptoms often overlap with other conditions such as dyslexia and ADHD. The results of one clinical trial supplementing with DHA, AA, linolenic acid (“LA”), Vitamin E and thyme oil showed statistically significant improvement in measures of movement performance after supplementation. A second study used a supplement containing 80% fish oil and 20% evening primrose oil. The second study did not show improvement for movement scores but demonstrated improvement for participants in reading, spelling and behavior measures. The studies suggested that fatty acid supplements may be a safe, tolerable and effective treatment for improving some symptoms of DCD.

C. Reviews of Research

The advertiser also submitted published reviews of studies on supplementation with Omega-3’s, including reviews of both observational studies and controlled clinical trials, and their impact on symptoms of ADHD, dyslexia, dyspraxia and autism spectrum disorders. The studies suggest that supplementation with Omega-3’s can have a positive effect on symptoms, though results are inconsistent, and that polyunsaturated fatty acids play a significant role with respect to normal neurological functioning. The advertiser submitted two additional reviews of research regarding supplementation with polyunsaturated fatty acids and mental health, mood and behavior. Both reviews concluded that the prior research studies demonstrate that supplementation may ameliorate the symptoms of these conditions and that Omega-3’s are important to normal brain function.

D. Additional Research

In addition to the published studies of clinical trials, the advertiser provided additional articles discussing the association of low levels of Omega-3’s and ADHD, dyslexia, dyspraxia and other

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behavioral problems. The articles discuss reasons for the association and potential benefits of supplementation. The advertiser also looked to articles regarding levels of Omega-3’s in breast milk and infant formula and their importance to healthy brain development and central nervous system function. The advertiser argued that these articles provided further support for its claims that Speak products support normal and healthy speech development and maintenance.

II. Oxidative Stress Support

In support of NourishLife’s claim that its Speak products provide a “reduction in oxidative stress” the advertiser noted that the Speak products contain both Omega-3 Fatty acids and Vitamin E. The advertiser asked NAD to note that Vitamin E is a known antioxidant. As support of its contention that Vitamin E can reduce oxidative stress, NourishLife relied on a series of articles on Vitamin E supplementation, its known properties as an antioxidant, and its ability to protect long-chain polyunsaturated fatty acids.

Further, the advertiser relied on articles about increased oxidative stress in conditions like autism and VA. One report, Metabolic biomarkers related to oxidative stress and antioxidant status in Saudi autistic children, noted that autistic children are under oxidative stress and deficient in vitamin E, “Since the brain contains high levels of oxidizable lipids that must be protected by antioxidants, so supplementation of autistic patients with vitamin E as the major lipophilic antioxidant in the brain could be helpful in the treatment of autism and other neurodegenerative diseases.” Another study, Oxidative Stress in Autism, noted that greater lipofuscin, a biomarker for oxidative injury, was measured in areas of the autistic cortical brain concerned with language and communication. Autistic children also have lower indirect markers for oxidative stress including, lower endogenous antioxidant enzymes and glutathione, lower antioxidant nutrients, higher organic toxins and heavy metals, higher xanthine oxidase and cytokines, and higher production of nitric oxide, a toxic free-radical. The study concludes, “Vitamin E may have concrete implications in autism or in healthy children prior to regression…Preliminary data suggest lower plasma vitamin E levels in autistic children.”

III. Testimonials

NourishLife maintained that its Speak products provide a significant benefit to many children and their families. It further maintained that its claims are fully supported by the substantiation provided to NAD and, as a result, its use of consumer testimonials on its website is also fully supported.

IV. Apraxia Research Website

The advertiser advised NAD that the website, www.apraxiaresearch.org, is owned and maintained by NourishLife. The advertiser, however, argued that the website serves as an informational and educational resource for consumers interested in learning about apraxia. It argued that there is no marketing or exposure of the Speak product on the website, the Speak products are not mentioned on the site, nor is it possible to purchase the Speak products through the website. NourishLife argued that pursuant to DSHEA, third-party literature and materials are only considered an extension of a brand if they have that brand on it. Further, in order to access the research article from NourishLife’s website, the user must click through a disclosure which provides:

The research articles and study abstracts that you are about to view in the ApraxiaResearch Library were prepared by independent authors and researchers. They are being reproduced on this site in their entirety. No such article or study abstract is intended to promote a particular manufacturer or brand of dietary supplement. This information is not intended to replace the advice of your health care practitioner. If you have any medical conditions, or are taking any prescription or nonprescription medications, see your physician and discuss all aspects of your treatment before altering or discontinuing any course of therapy. Accordingly, individuals must necessarily assume responsibility for their own actions, safety, and health, and the company is not liable or responsible for any loss, injury, or damage allegedly arising from any information posted on this site.

THIS INFORMATION IS BEING PRESENTED PURSUANT TO SECTION 5 OF THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994----THE “E” IN DSHEA—BROUGHT TO YOU AS A PUBLIC SERVICE BY NOURISHLIFE.

NourishLife argued that its third party literature follows the requirements of Section 5 of DSHEA.

Decision:

NourishLife markets dietary supplements under the name Speak that consist of a combination of fatty acids as well as Vitamins E and K. The Speak products claim that they support normal and healthy speech development and reduce oxidative stress. NourishLife licenses the formula and markets the Speak products for use by children. The formulation was developed by Claudia
Morris, a pediatrician at the Children’s Hospital and Research Center Oakland, CA, to provide dietary support to children with neurological developmental disorders like Verbal Apraxia. In addition, NourishLife owns and manages the website www.apraxiaresearch.org for consumers interested in learning about research regarding dietary supplements and developmental speech disorders. The advertiser contended that extensive research on fatty acids and Vitamin E, alone and in combination, supports its product performance claims. NAD is mindful that the advertiser’s product provides supplementation for a population struggling to find alternative therapies to aid in the development of healthy speech. NAD is equally mindful, however, of the need to provide accurate information to consumers, based on competent and reliable scientific evidence when the advertiser is making health-related claims.

I. Speech and Motor Skills Claims

The FTC explained in an advertising guide for dietary supplements in 2001 that “advertising for any product – including dietary supplements – must be truthful, not misleading and substantiated.” Advertisers are responsible for substantiating both express and implied claims in their advertising and must support all claims made in advertising, not just the claims they intended to convey. As a general rule, health-related advertising claims must be supported by competent and reliable scientific evidence. Such evidence generally comes in the form of well-controlled studies, the results of which translate into a meaningful benefit for consumers and relate directly to the performance attributes promised by advertising.

A. Establishment Claims

As an initial matter, NAD noted that NourishLife introduces its claims with the phrase, “Mounting clinical evidence” followed by “this special blend of nutrients provides targeted benefits.” Advertisers that make a “clinically proven” or “clinically tested” claim are held to high standard of proof because the claims are, in essence, a promise that there is scientific evidence that proves or establishes the truth of an advertiser’s claims. NAD considered whether a “mounting clinical evidence” claim reasonably conveys the message that the Speak products have been proven effective in providing the claimed benefits. In the absence of


23 Id.

24 WIPSS Products, Inc. (Brain Pad Head Gear), Report # 4139, NAD/CARU Case Reports (February 2004); Nutramax Laboratories, Inc. (Senior Moment Advanced Memory Enhancing Dietary Supplement), Report #3899, NAD/CARU Case Reports (April 2002).

25 A reasonable interpretation of a claim that a product is “University Studied” is that it has been clinically tested. NAD has consistently found that “a claim that a product is ‘clinically tested’ conveys a message that those test yielded positive results and reasonable consumers will interpret this claim to convey the same message as a clinically proven claim.” Syntratech Corp. (Syntra-5 Total Body Solution), Report # 5150 NAD/CARU Case Reports (March 2010).
consumer perception evidence, NAD uses its own experienced judgment to determine if there are any implied messages reasonably conveyed in an advertisement.26 A claim found to be implied by NAD need not be the only claim conveyed by an advertisement, it need only be one of the reasonable messages conveyed by an advertisement.27 NAD determined the phrase, “mounting clinical evidence” could be reasonably interpreted to mean that the products themselves have been tested and proven to provide the claimed benefits. This message is underscored as it is followed by the claim that “this special blend of nutrients provides targeted benefits,” which further implies that the product itself has been tested and found to be effective. Health-related establishment claims must be supported by competent and reliable scientific evidence that includes testing on the product itself that is grounded in sound methodology.28

NAD was concerned about whether the studies relied upon by NourishLife met the level of reliability necessary to support NourishLife’s establishment claims, particularly because establishment claims, as a general rule, must be supported by testing on the product itself or a mix of identical ingredients in the same quantities as in the advertised product.29 Only one study, the Morris/Agin Study, included any subjects who used the Speak products as a supplement. The Morris/Agin study was an observational study in which 187 children with verbal apraxia received polyunsaturated fatty acids and vitamin E supplements. Participants’ parents representing 97% percent of children in the study reported “dramatic improvements in a number of areas including speech, imitation, coordination, eye contact, behavior, sensory issues, development of pain sensation, and GERD30 symptoms.” Not all participants in the Morris/Agin study, however, used the Speak products. In fact, the dosage of Omega-3 and Vitamin E supplements taken by participants in the study were inconsistent. The study reported “a majority of families used supplements that contained 280 mg DHA and 695 mg EPA/dose in liquid or capsule form,”31 but that doses and brands of supplements varied.

26 See The Gillette Company (Fusion ProGlide Razors), Report #5299, NAD/CARU Case Reports (March 2011); See Nature’s Cure, Inc. (2-Part Acne Treatment), Report #4797, NAD/CARU Case Reports (February 2008).
27 See, Lenovo (United States), Inc. (Personal Computers) Report #4820, NAD/CARU Case Reports (March 2008); Sanderson Farms (Sanderson Farms Chicken), Report #4289, NAD/CARU Case Reports (March 2005); Atkins Nutritional, Inc. (Advertising for The Atkins Food Pyramid), Report # 4230, NAD/CARU Case Reports (September 2004); Snapple Beverage Corporation (Snapple-a-Day Meal Replacement), Report # 4132, NAD/CARU Case Report (January 2004)
28 Vitaenergy, Inc. (Urinozinc Supplements), Report #5433 NAD/CARU Case Reports (February 2012); see also Guidance for Industry: Substantiation for Dietary Supplement Claims made under Secion 403(r)(6) of the Federal Food, Drug, and Cosmetic Act at 5; see also http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm073200.htm.
29 See Good Living Labs, LLC (Good Days Herbal Supplement), #5101 NAD/CARU Case Reports (November 2009) (“NAD found that the advertising does not make it clear that the claims are based on limited testing on certain ingredients . . . Given the absence of any product testing, NAD recommended these claims be discontinued.”)
30 Gastroesophageal Reflux Disease
31 A dose similar to the 275 mg DHA and 725 mg EPA in the Speak products.
NAD was also concerned about whether the study methodology was sufficiently reliable to support a finding of a causal relationship between supplementation and improvements noted in the Morris/Agin study. Subjects’ parents reported their observations of their children’s experience with supplementation voluntarily through an online questionnaire. There were no objective or systematic measures for selecting the subjects or measuring improvement. The methodological shortcomings make it difficult to assess whether improvements were objectively measurable, what improvement might be a result of the “placebo effect” and whether those who reported results had the same results as users of fatty acid supplements who did not report. Finally, the purpose of the study was not defined as the impact of Omega-3 and vitamin E supplements on speech or language development, but rather to “characterize symptoms and metabolic anomalies of a subset of children with verbal apraxia.” This single observational, uncontrolled study does not provide the level of support required to substantiate establishment claims. As a result, NAD recommended that the advertiser discontinue its claim, “Mounting clinical evidence … indicate that this special blend of ingredients provides the targeted benefits.”

B. Efficacy Claims

NAD also considered whether the advertiser had provided sufficient support for an efficacy claim that the Speak products “support normal and healthy speech development and maintenance” and provide “nutritional support of verbal and motor skills.” Even if these claims are statements of nutritional support under the DSHEA, as NourishLife argued, the advertiser must have substantiation that such statements are truthful and not misleading. NAD has long held that such health-related efficacy claims must be supported by reliable, competent scientific evidence on the product itself.

Although, there is an abundance of research on the health benefits of Omega-3 fatty acids and NAD has reviewed advertising claims for products containing Omega-3 supplements in several prior decisions, NAD was concerned that the support provided by the advertiser in this case was insufficient to provide a reasonable basis for claims regarding the efficacy of the Speak products, as there was no testing on the product itself.

32 “Observational studies have a more limited ability than intervention studies to distinguish relationships between a substance and the outcomes being evaluated and cannot provide causal evidence.” Guidance for Industry at 10.
33 The study conclusion acknowledged the need for clinical trials and stated, “as a benign intervention, it may be worthwhile for providers to consider a trial of empiric supplementation as a complementary approach to VA in addition to traditional speech and occupational therapy while we await the funding and results of clinical trials.”
34 Dreambrands, Inc. (Add Lib), Report #5451 (March 2012)(“NAD noted that the Advertiser, to support its claims, was required to establish by means of competent and reliable scientific evidence that Testofen could be expected to produce the same results in females.”); Good Health Naturally, LLC (Serranol Supplements), Report # 5441 NAD/CARU Case Reports (March 2012) (“Advertisers bear the burden of producing competent and reliable scientific evidence in support of their clinically proven or health performance claims.”)
35 In prior cases NAD has recognized that the benefits of Omega-3 supplements include a beneficial impact on cognitive functioning, anti-inflammatory health benefits, and cardiovascular health benefits. See, e.g. Flora, Inc. (Udo’s Oil 3-6-9 Blend), Report #5389 NAD/CARU Case Reports (October 2011); The Coca Cola Company (Minute Maid Enhanced Juice Blend), Report # 5091 NAD/CARU Case Reports (September 2009); Schiff Nutrition Group (MegaRed Omega-3 Krill Oil), Report #4970 NAD/CARU Case Reports (February 2009).
nor was there testing on the supplementation of Omega-3 and Vitamin E in the dosages used in the Speak products. As a result, NAD recommended that the advertiser discontinue its efficacy claims that the Speak products “support normal and healthy speech development and maintenance” and provide “nutritional support of verbal and motor skills.”

C. Ingredient Claims

Given the substantial research on Omega-3 and Vitamin E supplementation submitted by the advertiser, NAD also considered whether the advertiser could make ingredient claims for its products, i.e. that the ingredients in the Speak product were designed to support speech development. NourishLife submitted many articles and studies on the benefits of polyunsaturated fatty acids, their function in the body, as well as several clinical studies on supplementation with Omega-3, both with and without Vitamin E, in children with a variety of neurological development disorders, including autism, ADHD and Developmental Coordination Disorder, to determine their impact on symptoms of those disorders.

Several clinical studies evaluated whether supplementation with Omega-3 fatty acids aids speech development. A study by Patrick and Salik recorded improvement in verbal skills in autistic children after supplementation with polyunsaturated fatty acids. The study, however, was an uncontrolled, open label trial on 22 subjects, only 18 of whom completed the study. The Patrick and Salik study used substantially lower doses of Omega-3 and Vitamin E than the amount of each in the recommended dose of the Speak products. The Meguid Study, noted “parents reported an improvement in … language development and motor skills,” but suffered similar shortcomings as it was also a small (30 participants), uncontrolled, open label study which also used lower doses of Omega-3 (than the amount in the Speak products) and did not include supplementation with Vitamin E. The Morris/Agin study, discussed more fully above, in which 187 children with verbal apraxia received polyunsaturated fatty acids and vitamin E

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36 See Body Dynamics, Inc. (Mega Cleanse), Report #5538 NAD/CARU Case Reports (December 2012).
38 Patrick and Salik Study used 90 mg DHA, 135 mg EPA, and 33 mg GLA and 15 IU of Vitamin E and Speak includes 275 DHA, 725 EPA, 60 mg GLA and 500 IU of Vitamin E in Speak. Id. The Speak products dosage instructions recommend that users begin by taking one capsule or ½ tbsp. per day and gradually increase their dosage up to 6 capsules or 3 tbsp. per day. The dosage on the label, included here for comparison, is the dosage included in 2 capsules or 1 tbsp of Speak.
40 Meguid Study used 240 mg DHA, 52 mg of EPA, 48 mg GLA, 20 mg AA and Speak includes 275 DHA, 725 EPA, 60 GLA.
supplements, though larger, was similarly uncontrolled, used inconsistent doses of Omega-3 and Vitamin E and also lacked objective standards for measuring improvement. NourishLife also relied upon two studies as support for the claim that supplementation with Omega-3 fatted acids improved motor skills. The Richardson study, a randomized controlled trial on 117 children with Developmental Coordination Disorder concluded that supplementation did not have a statistically significant effect on motor skills versus the placebo, but noted improvement in reading and spelling. The Stordy study noted improvement in movement and dexterity skills, but the study was a small, preliminary uncontrolled trial. Both studies found that there may be value in supplementation with PUFA’s to support children with specific learning disorders. Both studies, however, used different doses and types of fatty acids than Speak.

Additionally, several reviews of research submitted by the advertiser considered the impact of fatty acid supplementation on Autism Spectrum Disorder, ADHD, mood and behavior, and other childhood developmental delays. These reviews concluded that the research on fatty acid supplementation and its impact on various childhood development disorders continues to be uncertain and is still an emerging but promising avenue for future study. Study authors in three reviews concluded that the evidence for Omega-3 providing measurable support or improvement for verbal and motor skills is limited and inconsistent. The therapeutic potential of Omega-3 fatty acids to support children with neurological development disorders is promising, particularly surrounding whether a subset of children with neurological developmental disorders suffer from

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44 The Stordy Study used 480 mg DHA, no EPA, 96 mg GLA, and 35 mg AA. The Richardson Study used 174 mg DHA, 558 mg EPA, no GLA and 60 mg LA. Speak includes 275 DHA, 725 EPA, 60 GLA.

45 NourishLife also submitted articles related to supplementation with polyunsaturated fatty acids and dietary intake of Omega-3 fatty acids in pregnant women and infant children and its impact on the developing brain. A review of the available research concluded that studies are inconsistent but suggest the possibility that polyunsaturated fatty acids can optimize brain development in infants, but that further study is necessary. Carlson, S.E., Early Determinants of Development: a lipid perspective, Am. J. of Clin. Nutr. 89 (suppl):1523-9S (2009).

a functional Vitamin E and Omega-3 deficiency and, thus, may be responsive to nutritional intervention. However, results from clinical studies evaluating the impact of supplementation on verbal and motor skills have been inconsistent and, as a result, inconclusive.\footnote{See Schuchardt, J.P., et al, Significance of Long Chain PUFA’s for the development and behavior of children, Euro. J. Pediatr. 169:149-164 (2010).}

NAD noted that the research upon which the advertiser relied was emerging. The nature and extent of advertising claims should be directly analogous to the precision and specificity of the data used to substantiate them.\footnote{A.D. Pharma, Inc., Report #4163, NAD/CARU Case Reports (March 2004) at 6, citing Nutramax Laboratories, Inc. (Senior Moment Advanced Memory Enhancing Dietary Supplement), Report #3899, NAD/CARU Case Reports (April 2002) (“The nature and extent of the claims should be directly analogous to the precision and specificity of the data used to substantiate them.”)} The results of many of the clinical studies submitted suggest that Omega-3 supplementation might be an effective nutritional intervention for addressing some of the cognitive and neural development issues in several childhood development disorders, including Apraxia, DCD, ADHD and Autism. Additionally, supplementation with these ingredients may have particular benefits in children with an actual or functional deficiency in Omega-3 and Vitamin E. The research does not support the use of Omega-3 and Vitamin E supplements, however, to support normal and healthy speech development in children without such disorders. Further, although, the DSHEA allows statements of nutritional support, and was adopted expressly due to “the importance of nutrition and the benefits of dietary supplements to health promotion,” any statement of nutritional support must also be truthful, accurate and not misleading. NAD cautioned the advertiser that given nature of the research on Omega-3 fatty acid supplements and their impact on speech and motor skill development in children with neurological development disorders, any advertising claims based on such support should be limited both in claimed benefits and the population at whom the product is directed.\footnote{Id.} In general, claims that are based on emerging research of ingredients in a product should indicate the emerging and limited nature of the research in their advertising claims.\footnote{See Dietary Supplements: An Advertising Guide for Industry, Federal Trade Commission, \url{http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf}, (April 2001) (“Under FTC law, before disseminating an ad, advertisers must have a reasonable basis for all express and implied product claims. What constitutes a reasonable basis depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified. The FTC’s standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented in advertising.”)}

C. Oxidative Stress Claims

NourishLife also claims its Speak products reduce oxidative stress. As noted above, without testing on the product itself, the advertiser’s claims must be limited to ingredient claims that ingredients in the product can provide the claimed benefits. In support of an ingredient claim that Speak products reduce oxidative stress, the advertiser relied on a series of articles regarding
the function of Vitamin E in the human body and its role as an antioxidant.\textsuperscript{51} It is well-accepted that Vitamin E has antioxidant properties, “Vitamin E functions as a chain-breaking antioxidant that prevents the propagation of free radical reactions.”\textsuperscript{52} Although two articles were submitted by the advertiser in support of the relationship between Vitamin E and reducing oxidative stress,\textsuperscript{53} both articles discuss the dose of Vitamin E supplements that can impact isoprostanes, a biomarker of oxidative stress, in adults with symptoms of cardiovascular disease. The advertiser provided no research, however, linking Vitamin E supplementation to reducing oxidative stress in children, the target of the advertiser’s claims.\textsuperscript{54} As a result, NAD recommended that the advertiser discontinue its claim that the Speak products provide a reduction in oxidative stress in children.

II. Website

The advertiser maintains a website, www.apraxiaresearch.com. The website does not indicate that it is maintained by NourishLife nor does it mention NourishLife or the Speak products. The website’s purpose appears to be to educate visitors about Verbal Apraxia. It provides links to the following information:

- The Morris/Agin Verbal Apraxia study;
- Basic information about Verbal Apraxia;
- Enrollment information for a study on Verbal Apraxia and supplementation with Omega-3 and Vitamin E;
- Additional research on Verbal Apraxia and related conditions; and
- Testimonials from parents whose children have used supplements to treat Verbal Apraxia, and other nutritional suggestions for treating Verbal Apraxia.

The advertiser argued that because the website does not solicit sales of its product or even mention the product, it is not a promotional website and should not be subject to NAD’s review.

In past decisions NAD has reminded advertisers of their obligation to inform consumers when they are advertising to them. Both NAD and the FTC have reminded advertisers of their

\begin{footnotes}
\item Dreambrands, Inc. (Add Lib), Report #5451 (March 2012)(“NAD noted that the Advertiser, to support its claims, was required to establish by means of competent and reliable scientific evidence that Testofen could be expected to produce the same results in females.”)
\end{footnotes}
obligation to advise the public that what they are reading is commercial speech. In a 1968 Advisory Opinion, the FTC questioned the use of a news feature and/or article that purported to provide an impartial view of a restaurant, when the column was paid for by the advertiser. The [www.apraxiareserch.com](http://www.apraxiareserch.com) website appears to be an independent website, however, it is maintained by NourishLife.

In a prior case, NAD noted that the maker of cellphone blue tooth headsets that distributed a YouTube video showing popcorn kernels being popped by a cellphone was advertising, although the advertiser never mentioned its name or product in the video. Similarly, NAD recommended that an advertiser that maintained a blog, Prostate Health Blog, linked to its website, which communicated helpful information about prostate health, clearly and conspicuously disclose that the blog was written and maintained by the advertiser. These recommendations are consistent with the FTC Guide to endorsement and testimonials, which reminds advertisers that they can be held liable for failure to disclose material connections between themselves and a party or entity endorsing a product. Here NourishLife has not disclosed a material connection between itself and [www.apraxiareserch.com](http://www.apraxiareserch.com). To avoid the potential for consumer confusion, NAD recommended that NourishLife modify the website to disclose in a clear and conspicuous manner that the website is maintained by NourishLife.

III. Testimonials

NourishLife claims that “hundreds of parental reports indicate this special blend of nutrients provides targeted benefits.” Additionally, NourishLife’s website includes testimonials under a link for “Community Resources” in which parents discuss their children’s speech improvements after taking Speak supplements. NAD has routinely held that an advertiser may not make claims through consumer testimonials that could not be substantiated if made directly by the advertiser and that anecdotal evidence, based solely on the experiences of individual consumers, is insufficient to support product efficacy claims. Because NAD determined that the underlying claims for the Speak products were unsupported, NAD recommended that NourishLife discontinue its use of testimonials containing product efficacy claims and its claim that “hundreds of parental reports indicate this special blend of nutrients provides targeted benefits.”

Conclusion:

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55 See Advisory Opinion No. 191, 73 FTC 1307 (File No. 6683 7080, released Feb. 16 1968). The FTC issued guidelines to newspapers and print mediums suggesting that any advertisement in the news or feature article format be prominently accompanied by the word “ADVERTISEMENT”
57 Herbal Groups Inc. (Prostalex Plus), NAD/CARU Case Reports, Report #5005 (July 2009).
59 Flora, Inc. (Udo’s Oil 3-6-9 Blend), #5389 NAD/CARU Case Reports (October 2011); The Elations Company, LLC (Elations Liquid Supplements), Report #5196, NAD/CARU Case Reports (July 2010).
As a preliminary matter NAD noted in appreciation for the advertiser’s offer to voluntarily and permanently discontinue the following claims: (1) Pharmaceutical Grade; (2) See benefits as soon as the first week; (3) Others notice advances in speech and coordination after several weeks; (4) The combination of omega-3 within vitamin E together had a dramatic impact on these children’s symptoms, not only helping with speech, but also improved eye contact and helping to improve pain sensation; and (5) A patented nutritional therapeutic formulation designed for the treatment of apraxia, an action NAD found to be necessary and appropriate.

NAD determined that the advertiser’s evidence was insufficient for its claims that the Speak products provide nutritional support of verbal and motor skills and normal and healthy speech development and reduce oxidative stress. NAD also recommended that the advertiser discontinue its claim, “mounting clinical evidence and hundreds of parental reports indicate this special blend of nutrients provides targeted benefits” as it lacked the required substantiation to make an establishment claim. NAD further recommended that the advertiser discontinue its use of testimonials to the extent the testimonials make unsupported product efficacy claims, as it lacked support for the underlying claims.

Finally, NAD recommended that the advertiser modify the www.apraxiaresearch.com website to disclose in a clear and conspicuous manner that NourishLife created and maintains the website.

Advertiser’s Statement:

NourishLife fully supports and agrees with the NAD’s goal of sustaining truth and accuracy in advertising and takes this responsibility to the consumer very seriously. NourishLife is confident in the science behind the formulation of nutrients contained in our speak product. Furthermore, NourishLife appreciates NAD’s viewpoint that “NAD is mindful that the advertiser’s product provides supplementation for a population struggling to find alternative therapies to aid in the development of healthy speech.” (NAD decision, 2013) NourishLife has enlisted the support of numerous scientists and experts in the field in our efforts to have reliable and competent scientific evidence. While the NAD asserts that the science behind the speak product is emerging, NourishLife maintains that the body of science sufficiently supports the claims made. However, with the combined goal of full cooperation with advertising self-regulation, NourishLife has voluntarily discontinued certain claims and agrees to take NAD’s recommendations into consideration in future marketing materials and advertising. (#5620 LB, closed 08/08/2013)