



A service of the advertising industry and Council of Better Business Bureaus

Dietary Supplements and Functional Foods Digest

About the National Advertising Division: NAD is an investigative unit of the advertising industry's system of self-regulation. It is administered by the Council of Better Business Bureaus.

NAD seeks to ensure that claims made in national advertising are truthful, accurate and not misleading. NAD requires that objective product performance claims made in advertising be supported by competent and reliable evidence.

NAD cases can be initiated through staff monitoring of advertising claims or through "challenges" to advertising claims filed by competitors, consumers, or public interest groups.

NAD attorneys are experts in advertising claim substantiation and decisions are based on precedent. More than 90 percent of the advertisers who come before NAD comply with NAD's recommendations.

To encourage participation, NAD seeks to provide a user-friendly service. NAD's case manager works closely with parties to facilitate scheduling and the NAD assistant director, communications, provides one-on-one assistance with navigating the NAD process.

NAD's time to decision varies with the complexity of the case and needs of the parties. NAD recognizes that parties may occasionally seek deadline extensions; NAD works to ensure that reasonable extensions are granted after consultation with both parties.

Following are excerpts from dietary supplements and functional foods cases decided by NAD. Each case involves consideration of the claims made in the advertising and labeling and the supporting evidence provided by the advertiser.

VH Nutrition, Inc.
TriDrive Dietary Supplement
Case #6197 (06.21.18)

NAD recommended VH Nutrition discontinue certain advertising claims for the company's TriDrive dietary supplement, a product promoted to triathletes through internet advertising. NAD requested that VH Nutrition provide substantiation for advertising claims that included "TriDrive is a triathlon supplement that helps to give a Vo2 Max boost. It uses a complex formula of adaptogen supplements that help boost endurance, improve circulation, and support the respiratory system."

NAD determined that the challenged claims are health-related in nature and, as such, must be supported by competent and reliable scientific evidence. Generally, NAD noted, such evidence consists of human clinical trials that are methodologically sound and statistically significant to the 95% confidence level with results that translate into meaningful benefits for consumers that relate directly to the performance attributes promised by advertising.

The advertiser did not submit testing on the TriDrive product itself, but instead relied on evidence that studied the efficacy of the ingredients in TriDrive. NAD noted in its decision that it is "well-established that when there is substantiation only for the efficacy of ingredients in a product, but not for the product itself, any claims must be clearly expressed as ingredient claims."

NAD then examined whether the advertiser's evidence was sufficient to support carefully tailored ingredient claims, noting that while advertisers may make properly qualified claims based on ingredients in their supplements, those ingredients must be present in their products in the same amount, formulation and route of administration as the underlying ingredient studies. The ingredient studies, NAD noted, must also be of sufficient quality to be competent and reliable scientific evidence and, also, relate directly to the claim promised by the advertising.

NAD determined that the ingredient studies did not reflect the formulation of TriDrive. Consequently, NAD recommended that the advertiser discontinue its health-related performance claims regarding TriDrive supplement as a whole and recommended the advertiser discontinue the following claims:

- "TriDrive is a triathlon supplement that helps to give a Vo2 Max boost. It uses a complex formula of adaptogen supplements that help boost endurance, improve circulation, and support the respiratory system."
- As an adaptogen it "works slowly with your body over time to give you access to faster recovery and improved stamina."
- "TriDrive is a support to cycling nutrition as well by helping your body process nutrients faster and overcome stress quicker. It is also one of the best runner supplements that helps to ease joint stress by improving recovery time for your muscles."
- "Boost VO2Max"

- “Improve Stamina”
- “Decrease Cortisol Production”
- “Endurance Recovery”
- “TriDrive help improve oxygen flow with the body during exercise.”
- “Overcome stress quicker.”

NAD noted that nothing in its decision prevents the advertiser from making truthful and accurate claims regarding the traditional use of the ingredients in TriDrive.

In its advertiser's statement, VH Nutrition noted that for business purposes, TriDrive is no longer being sold but that if TriDrive were to be sold in the future, it would comply with NAD's recommendations.

i-Health Inc.

Culturelle

Case #6196 (06.20.2018)

NAD recommended that i-Health discontinue advertising claims made in television and online advertising, and on product packaging for its Culturelle probiotic supplements. The claims at issue, challenged by The Procter & Gamble Company (maker of Align probiotic supplements), included “Exclusively with the #1 Proven Effective Probiotic*”; *Based on the studies of a range of benefits throughout the lifespan. *In close proximity to the claims: “works naturally with your body to keep your digestive system in balance,” “helps with occasional digestive upset, including diarrhea, gas and bloating,” and “helps your digestive system work better,” and “Culturelle supports digestive health in overall wellness with the most proven effective probiotic”* NAD also considered whether the advertising at issue implied that i-Health's LGG is the most effective probiotic in terms of overall health-related benefits or is the most effective probiotic in balancing the digestive system, supporting immune health, and treating diarrhea, gas, and bloating.

NAD noted in its decision that probiotics are identified by three markers: first, the genus, which indicates a group of closely related species; second, the species, which indicates a group of individual bacteria that share certain similarities, and finally, the strain, which is the unique identifier for the specific ingredient. Importantly, not all species of probiotics are part of the normal human gut flora and the beneficial effects attributed to one strain cannot be generalized to other strains. For these reasons, NAD determined that there is a potential for consumer confusion regarding the specific beneficial attributes of any probiotic. As more strains are discovered, researched and introduced to the marketplace, NAD noted, the potential for confusion rises.

In support of the challenged claims, the advertiser provided a numerical count of studies, sourced from the PubMed clinical studies repository, based on “positive outcomes” and “positive primary outcomes.” NAD had several significant concerns with this approach. NAD was also not convinced by the advertiser's argument that the claims at issue were not comparative in nature. Following its review,

NAD determined that at least one message reasonably conveyed by the claim “most clinically proven effective” is that Culturelle is more effective than competing products at providing the benefits associated with probiotics. When considered in light of the other health-related advertising claims made in close proximity to the claims, such as “helps with occasional digestive upset, including diarrhea, gas and bloating” and “it’s the only one you need to help support good digestion and immune health,” NAD determined one reasonable interpretation would be that the advertiser’s LGG ingredient has been clinically proven to be the best probiotic on the market for treating various types of occasional digestive upset and supporting immune health. NAD noted in its decision that the use of the terms “most clinically proven effective” and “#1 clinically proven effective” indicate to consumers that there is scientific evidence that proves or “establishes” the truth of the advertiser’s claim. Without comparative studies in support of the advertiser’s claim, NAD could not evaluate whether the strain of probiotic in Culturelle was the “#1 clinically proven,” or “most clinically proven.” Further, unqualified comparative superiority claims require substantiation against all significant competitors in the product category, evidence which was not provided here.

NAD concluded that the advertiser’s evidence was not a good fit for the messages reasonably conveyed by the challenged claims and recommended that the advertiser discontinue its “most proven effective,” “most clinically proven effective,” and “#1 proven effective” claims.

i-Health agreed to comply with NAD’s recommendations.

Abbott Nutrition
Ensure Nutrition Products
Case #6195 (06.15.18)

NAD recommended that Abbott Nutrition discontinue claims that promise consumers they will “Feel More Strength & Energy in Just 2 Weeks.” NAD also found that the company could support claims that its “Ensure Surgery” product is the “#1 Doctor Recommended Brand.”

The nutritional beverages made by the challenger and the advertiser are formulated to provide a combination of calories, nutrients, and protein designed to supplement the diets of various vulnerable populations, including older adults. Animated commercials featuring the challenged strength and energy claim are set inside a refrigerator, where a bottle of Ensure Original gives a pep talk to other foods and beverages, encouraging the group to help “get the lady of the house back on her feet and help her feel more strength and energy in just two weeks.”

Following its review, NAD determined that one of the messages reasonably conveyed is a sensory claim – consumers using Ensure will feel stronger and more energetic after two weeks. NAD found that the advertising also conveyed the implied message that consumers would feel stronger and have more energy after two weeks because

adding Ensure to their diets actually made them stronger and more energetic – an objective performance claim.

NAD was unpersuaded by the advertiser's assertion that the only reasonable message conveyed by its advertising is that Ensure users self-reported feeling more strength and energy after two weeks. The advertiser relied on the results of a four-week in-home use test on Ensure Original as support for the claim. Following a screening process, participants were asked a series of questions at baseline to assess how they felt physically and emotionally prior to introducing Ensure into their daily diets. The participants were then asked to use the product and required to re-take the same questionnaire each week.

NAD noted in its decision that when a claim conveys a message about both the tangible, objective results of product use, as well as the subjective feeling of those results, objective testing is appropriate. NAD determined that the evidence provided was insufficient to support the implied claim that the consumers that use Ensure will have more strength and energy after two weeks and recommended that the express claim be discontinued.

NAD also considered whether Abbott's in-home test could support a more limited sensory claim and determined that the test was flawed and did not produce results that were sufficiently reliable to support the sensory claim at issue.

With regard to the use of "#1 Doctor Recommended Brand" in advertising for Ensure Surgery, the advertiser noted that it used the same version of its "#1 Doctor Recommended Brand" claim that NAD found substantiated in a prior matter. The advertiser stated that it regularly updates the survey used to substantiate this claim and that the claim remains truthful. While there are unique ingredients in Ensure Surgery, as there are in each sub-branded product, NAD noted that fact alone does not mean that the advertiser should be barred from utilizing brand recognition in its advertising for the product. NAD determined that the claim was substantiated.

Abbott agreed to comply with NAD's recommendations.

**Bel Marra Health
Hearing Rescue**

Case #6193 (06.13.2018)

NAD recommended that Bel Marra Health discontinue certain claims for the company's Hearing Rescue dietary supplement, including the claim that "vitamins and minerals such as folate and magnesium may help reduce the damage caused by repeated noise exposure," following a challenge by the Council for Responsible Nutrition (CRN).

During the course of NAD's review, the advertiser advised NAD that it would permanently discontinue the following claims:

- “Improve the volume, range and sensitivity of your hearing”
- “Relieve annoying ringing, whistling, and buzzing in the ears – starting in three weeks or less!”
- “In a clinical study of participants with sudden hearing loss, a whopping 79.2% of patients experienced better hearing after taking this amazing hearing-booster”
- “And two-thirds of patients saw a significant decrease in the ringing in their ears”
- “In as little as 7 days you can start to see the difference”
- Testimonial: “I’ve had hearing problems for the past 6 years...within a few weeks of taking Hearing Rescue, it helped me to hear sounds I haven’t heard in years.”

Given the advertiser’s representation, NAD did not review the claims on their merits. For compliance purposes, the voluntarily discontinued claims and testimonial will be treated as though NAD recommended the claims be discontinued and the advertiser agreed to comply.

The advertiser also said it had modified the following claims to make general antioxidant and nourishment claims:

- “Boost circulation to the tiny capillaries in and around your auditory canal”
- “Deliver the high potency, cell nourishing support to repair your inner ears”
- “Fight the free radical damage that can harm your hearing cells”

For compliance purposes, the modified claims will be treated as though NAD recommended their modification and the advertiser agreed to comply.

NAD noted in its decision that while advertisers may make properly qualified claims based on ingredients in their supplements, those ingredients must be present in their products in the same amount, formulation and route of administration as the underlying ingredient studies.

The studies submitted by Bel Marra assessed individual ingredients in the product. In all but one of the studies, the amount of the ingredient tested differed from the amount of the ingredient found in the product. Without testing that the ingredients in the quantity found in Hearing Rescue have the claimed effect, the results from these studies cannot be used to support qualified claims that the same ingredients in the product reduce the damage caused by repeated noise exposure and improve hearing. Following its review of the advertiser’s evidence, NAD determined that the claim “[s]ome evidence exists that suggests free radicals play a role in noise-related hearing impairment” was supported.

NAD determined that the advertiser’s claim that folate “provide[s] support in populations with low levels of folic acid” had a reasonable basis. However, because many of the advertiser’s claims involve noise-related hearing loss, in order to avoid confusion, NAD further recommended that the advertiser modify its claim to indicate the study population on which the claim is based – individuals with age-related hearing loss.

Finally, NAD determined that the claims “Contains a combination of 9 vitamins, minerals, and other ingredients,” “Contains ingredients that possess antioxidant abilities,” and “Fortified with Ginkgo biloba extract and alpha lipoic acid” were supported.

Bel Marra agreed to comply with NAD's recommendations.

NutriFrontier Pte Ltd
NutriO2 Dietary Supplement
Case #6185 (05/01/2018)

As part of NAD's initiative with the Council for Responsible Nutrition (“CRN”) designed to expand NAD review of advertising claims for dietary supplements, CRN challenged certain advertising claims and testimonials disseminated by NutriFrontier Pte Ltd. for its NutriO2 dietary supplement including: “The fact is that disease causing germs, bacteria and viruses cannot live in an oxygen-rich environment! In other words, wherever you have high levels of oxygen in your body, harmful bacteria and viruses are killed”; and “With just a few drops of NutriO2, in water three times a day, you are GUARANTEED to get the massive healing and immune boosting power of increased oxygen in your body...WITHOUT nasty, stomach problems, WITHOUT hit or miss results, WITHOUT needing to sit in an expensive oxygen chamber.”

In light of the advertiser's failure to provide a substantive response to NAD's request for substantiation for the challenged claims or participate in any way in the self-regulatory process, NAD is referred this matter to the Federal Trade Commission for possible enforcement action, pursuant to section 2.10 (A) of the ASRC Policies & Procedures.

In correspondence to NAD dated 6.28.18, the FTC informed NAD that following its inquiries into NutriFrontier's advertising claims, the company's website has since been deactivated. The FTC also noted that it was informed by NAD that the company would participate in the self-regulatory process and that no enforcement action was warranted as a result.

That's Natural, LLC
CBD Hemp Oil
Case #6173 (04/03/2018)

As part of its routine monitoring program, NAD requested substantiation for That's Natural's claim that “CBD makes cancer cells commit ‘suicide’ without killing other cells.”

The advertiser chose not to participate in this NAD proceeding. NAD noted that the advertiser claims that its product can kill cancer cells, an impactful claim targeting a vulnerable population. Given the potential impact of this claim, NAD was disappointed that the advertiser declined to participate in the self-regulatory forum's inquiry into the truth and accuracy of these claims. In light of the advertiser's failure to

provide a substantive response to NAD's request for substantiation for the challenged claim, or participate in the self-regulatory process, pursuant to Section 2.10(B) of the NAD/NARB Procedures, NAD will refer this matter to the appropriate regulatory agency for possible law enforcement action.

Evolution Nutraceuticals, Inc.

Cardio Miracle

Case # 6172 (04.30.2018)

NAD findings: CardioMiracle makes serious health-related claims such as, lowering blood pressure, optimizing blood flow, curbing nerve pain, lessening dizziness, fighting against gum disease and preventing heart attacks and strokes. NAD determined that the advertiser did not provide sufficient evidence to demonstrate that CardioMiracle, or the ingredients of CardioMiracle, deliver the advertised benefits to consumers. For the product itself, no clinical testing on the product as a whole was provided; even though the gold standard in health-related claims requires human clinical testing. Lacking this type of evidence, NAD found the claims to be unsubstantiated and recommended that the advertiser discontinue the claims related to the product.

NAD also took issue with CardioMiracle's ingredient claims because ingredients must be present in the product in the same amount, formulation and route of administration as the underlying ingredient studies. Here, the advertiser did not submit any studies to support its claims, including human clinical trials examining health-related effects of any ingredient in CardioMiracle. Therefore, NAD determined that the advertiser did not provide a reasonable basis for any of the health-related claims by the mere presence of Arginine and Citrulline in CardioMiracle. The presence of Astragin, an absorption enhancer, is insufficient to demonstrate that there are no undesirable interactions with the other ingredients in the product. Even though the Astragin was provided to the advertiser a third party supplier, who had done both in-vitro and in-vivo testing, the advertiser failed to submit these actual studies. For these reasons, NAD recommended the advertiser discontinue the claims and testimonials regarding both CardioMiracle's abilities and the ingredients present in the product.

Evolution Nutraceuticals, Inc.

Cardio Miracle

Case # 6168 (3.28.18)

Evolution Nutraceuticals was unable to support advertising claims and testimonials for its Cardio Miracle dietary supplement reviewed by the Council for Responsible Nutrition. Cardio Miracle is a powdered supplement that may be added to water or juice and consumed as a beverage with well over twenty ingredients. Evolution Nutraceuticals makes powerful, health-related claims that Cardio Miracle will—within days—lower blood pressure, optimize blood flow, cure nerve pain, dizziness, gum disease, and prevent heart attacks and strokes. CRN was concerned that the claims for Cardio Miracle reference serious medical conditions such as stroke, heart attack, neuropathy, and periodontal disease, and that consumers who forgo conventional medical treatment based on these claims may have serious health implications if the

claims are not adequately supported. Health-related claims should be supported by competent and reliable evidence, with the gold standard being human clinical testing on the product itself. Because Evolution Nutraceuticals did not submit any studies on the Cardio Miracle product itself, NAD recommended that the advertiser discontinue all of the challenged claims.

Evolution Nutraceuticals also did not submit any studies in support of its claims, including human clinical trials examining the health-related effects of any ingredient in Cardio Miracle. When there is substantiation only for the efficacy of ingredients in a product, but not for the product itself, any claims must be clearly expressed as ingredient claims. Because there was no evidence to support the claims, NAD recommended the claims be discontinued. Even if Evolution Nutraceuticals had submitted studies on the ingredients in Cardio Miracle, NAD would still have been concerned with the bioavailability and efficacy of any specific ingredient.

Cardio Miracle agreed to comply with all of NAD's recommendations.

Pharmavite, LLC

NatureMade Omega-3 with Xtra Absorb Technology Dietary Supplement

Case # 6152 (1.23.18)

A challenge brought by RB, LLC, a manufacturer of a competing product, MegaRed Omega-3 dietary supplement, against Pharmavite for its NatureMade Omega-3 Xtra Blend Dietary Supplement will be referred to the proper government agency based on Pharmavite's decision not to comply with NAD's recommendation that it discontinue its claim that NatureMade is "Nearly 4X Better Absorption* *than standard fish oil concentrate.

Both of the parties' omega-3 dietary supplements use the same self-microemulsifying drug delivery system ("SMEDS") technology. The recommended daily intake of Nature Made is one capsule containing 500 mg of EPA/DHA omega-3 fatty acids. Because the claim is a health-related advertising claim, Pharmavite need to show that the basis for extrapolating the absorption factor at 500 mg EPA/DHA is grounded in competent and reliable scientific evidence. The main issue was whether the absorption factor of Nature Made supplements could be reliably extrapolated from the study submitted by Pharmavite, which examined the absorption of higher amounts of EPA and DHA. It was uncontested that at some point below the tested dose, the absorption of EPA/DHA was not linear and may not be predicted by a linear regression analysis. The dose at which that occurs was unknown. Pharmavite did not provide competent and reliable scientific evidence that its linear regression analysis could reliably predict any absorption multiplier for a 500 mg EPA/DHA dose with SMEDS technology. Therefore, NAD recommended that claim be discontinued.

Pharmavite refused to comply with NAD's recommendation. Consequently, NAD referred the matter to the appropriate government authority pursuant to Section 2.9(B) of the *NAD/NARB Procedures*.

GSK Consumer Health

Citrucel®

Case # 6144 (12.22.17)

NAD found that extraordinary circumstances existed to reopen a case from 1994 concerning claims made by GSK Consumer Health (then SmithKline Beecham) for its Citrucel product (NAD Case Reports No. 3134).

P&G, the maker of Metamucil, argued that NAD should reopen the 1994 case in which NAD determined that GSK could claim that Citrucel “doesn't produce excess gas” as compared to “all other bulk fibers” provided that it discloses that the claims are based on “laboratory results, not human testing.” Absent extraordinary circumstances, NAD will not accept materially similar complaints based on claims already adjudicated. Here, the challenged claims, taken together, were materially similar to those at issue in the 1994 case because of their focus on the fermentability and excess gas caused by psyllium as compared to methylcellulose. The existence of *in vivo* studies, which directly relate to the digestion of fiber in the human body and the consequences thereof, rose to the level of extraordinary circumstances because the earlier request for reconsideration 20 years ago centered on additional *in vitro* studies which purportedly contradicted NAD's findings.

GSK established a reasonable basis for advertising claiming that Citrucel, a fiber supplement FDA-approved for laxation, is “NON-FERMENTABLE.” P&G argued that significant scientific developments have occurred since NAD rendered the 1994 Citrucel decision. GSK advertised that Citrucel (but not Metamucil) is “NON-FERMENTABLE” and “DOESN'T CAUSE EXCESS GAS” because Citrucel does not contain psyllium, while Metamucil does. When NAD evaluated the evidence in the underlying decision, both parties had cited almost exclusively *in vitro* studies which assessed the fermentability of psyllium and/or whether it caused excess gas.

While NAD considered both *in vitro* and *in vivo* studies, given the nature of the claims and the procedural posture of the case, NAD focused on the *in vivo* studies submitted by GSK because the *in vivo* studies related directly to the digestion of fiber in the human body and the consequences thereof. Neither the subjective nor objective measurements of gas production in the *in vivo* studies demonstrated that psyllium produced excess gas as compared to placebo, even at doses that are greater than the maximum daily recommended doses. Also, the totality of the evidence in the record on the relationship between psyllium and excess gas was inconclusive.

While some *in vivo* studies provided some evidence that psyllium may cause excess gas, they did not support the message reasonably implied by the advertising that psyllium always causes excess gas.

Although GSK Consumer Health established a reasonable basis for its claim that Citrucel does not cause excess gas, NAD concluded that GSK did not provide a reasonable basis for the claim that Metamucil always causes excess gas. The

challenged claims are health-related claims and center on whether psyllium (present in P&G's Metamucil but not Citrucel) ferments and causes excess gas.

In order to avoid conveying the unsupported message that psyllium always causes gas as is reasonably communicated in the advertiser's chart which indicates, using a check mark, that Citrucel does not cause excess gas and indicating by the absence of a checkmark that Metamucil does cause excess gas,) NAD recommended that GSK Consumer Health discontinue the "doesn't cause gas" claim in the comparison chart or modify it to avoid conveying the message that Metamucil always causes excess gas.

NAD also recommended that GSK discontinue the claim "The Only Fiber For Regularity that WON'T CAUSE EXCESS GAS*" or modify it to avoid conveying a message that Citrucel is the only product with methylcellulose. GSK expressly claimed that Citrucel is the only fiber for regularity that won't cause excess gas and attempts to qualify this claim by stating "among the top 5 national brands." NAD determined that this disclaimer, even if clear and conspicuous, contradicts the main claim because 15 percent of the marketplace (i.e., MiraFiber and other private label products) also contain methylcellulose, the same active ingredient in Citrucel.

GSK agreed to comply with NAD's recommendations.

Cebria, LLC
Cebria Supplements
Case # 6142 (12.19.17)

Cebria is a self-described "patented blend of neuropeptides" that claims to improve memory. Cebria sells its supplements through its commercial website and also hosts a YouTube channel that includes video testimonials claiming that Cebria will improve memory. Cebria argued that NAD should close the inquiry because the Federal Trade Commission has already reviewed the challenged claims and found them to be sufficiently substantiated. However, NAD determined that it had jurisdiction over dietary supplement claims that make the types of broad, establishment and quantified performance claims such as the advertiser made here.

NAD recommended that Cebria discontinue numerous advertising claims for its supplement that purported to improve memory. Cebria did not submit any clinical testing on the Cebria product as a whole, but rather submitted testing on the main ingredient in Cebria, N-PEP-12. When there is substantiation only for the efficacy of ingredients in a product, but not for the product itself, any claims must be clearly expressed as ingredient claims. Thus, NAD recommended that Cebria discontinue its claims that Cebria has the benefits claimed in its advertising. However, NAD examined the proffered studies on the main ingredient, N-PEP-12, to determine if they were sufficient to support properly qualified ingredient health claims for Cebria.

Cebria claimed that it has clinical proof that Cebria "creates a significant improvement in memory," "aids in protecting memory" and that it "builds new neuro-

connections," "improves memory in "30 days" and will help people with normal age related memory concerns "think faster and remember more." In support of these claims, Cebria relied on one double-blinded, placebo-controlled, randomized, peer-reviewed, published study on the main ingredient in Cebria, N-PEP-12. Even where some methodological virtues are present, studies must also provide enough information to permit a determination that overall the study was conducted in a manner that would yield reliable results that would be meaningful to the consumers to whom the advertising is targeted. In this case, NAD found inconsistencies among the study test results concerning, especially considering the strong health-related performance claims at issue. The record was devoid of competent and reliable scientific evidence that would indicate a level of improvement that would be meaningful to people with age-related memory concerns. Also, NAD had concerns that the results were not a good fit for the memory improvement and protections claims. Nothing prevented Cebria from explaining that N-PEP-12, an ingredient in Cebria, worked to build new neuro-connections in animals.

NAD also recommended that Cebria, LLC discontinue testimonials concerning the efficacy of the dietary supplement. Testimonials must not make claims that could not be substantiated if made directly by the advertiser. Also, anecdotal evidence, based solely on the experiences of individual consumers, is insufficient to support product efficacy claims. Here, the testimonials reasonably conveyed the same strong unqualified memory and cognitive improvement claims made by Cebria, which NAD determined were not supported. The disclosure "results may vary" was insufficient to cure the misleading messages conveyed by the claims.

Cebria appealed NAD's decision in its entirety.

Opiate Freedom Center
Opiate Freedom Center Dietary Supplement Systems
Case # 6128 (10.30.17)

As part of its routine monitoring program and in conjunction with NAD's initiative with the Council for Responsible Nutrition designed to expand NAD's review of advertising claims for dietary supplements, NAD requested substantiation for claims made by Opiate Freedom Center that its supplements were effective for at-home relief from drug addiction and would speed detox. Opiate Freedom Center failed to provide a substantive response to NAD's request for substantiation for the challenged claims or participate in any way in the self-regulatory process. Therefore, the matter was referred to the FTC.

FemaLife Nutrition, LLC
Super Flora Probiotic
Case # 6116 (9.17.17)

CRN had requested that NAD examine claims for FemaLife's Super Flora Probiotic to determine if FemaLife had adequate evidence to support its health-related advertising claims and testimonials. Because FemaLife failed to file a substantive written response

or provide any evidence to substantiate advertising challenged by the Council for Responsible Nutrition (CRN), NAD referred the matter to the FTC.

Following a referral of this matter to the FTC for failing to provide NAD a substantive or any evidence to substantiate the challenged claims, the advertiser advised NAD in writing that, instead of submitting substantiating evidence, it permanently discontinued the challenged claims and that Super Flora Probiotic is not available for sale. In reliance on the advertiser's representations that these claims had been permanently discontinued and that the product is no longer being sold, NAD did not review these claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

SuperFlora Probiotic accepted NAD's decision and represented that the advertising at issue has been voluntarily, permanently discontinued.

Eu Natural, Inc.

Stone Breaker Kidney & Gallbladder Cleanse Dietary Supplement

Case # 6113 (9.5.17)

Eu Natural, Inc. permanently discontinued advertising claims challenged by The Council for Responsible Nutrition (CRN). CRN requested NAD examine certain claims made by Eu Natural for its Stone Breaker Kidney & Gallbladder Cleanse supplement to determine if the advertiser possessed a reasonable basis for its claims. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended on the merits that it be discontinued and that the advertiser agreed to comply with NAD's recommendations.

Eu Natural supports the efforts of the Council of Responsible Nutrition and the NAD.

Deep Sea Nutrition, LLC

Ocean's Bounty Diabetes Dietary Supplements

Case # 6110 (8.28.17)

The Council for Responsible Nutrition (CRN) challenged certain Internet advertising claims made by Deep Sea Nutrition, LLC for its Ocean's Bounty diabetes dietary supplement. CRN expressed concern regarding the nature of the claims, which reference serious medical conditions such as diabetes, infection, and blot clots. Deep Sea Nutrition no longer promotes or sells Ocean's Bounty Diabetes supplements. NAD confirmed that the website with the challenged claims has been removed and administratively closed this proceeding.

Olly Public Benefit Corporation

Kids Mighty Immunity Supplements

Case # 6068 (3.27.17)

The Council for Responsible Nutrition (CRN) challenged Olly Public Benefit Corporation's Internet advertising and product packaging for its Kids Mighty Immunity dietary supplement. NAD found that Olly supported the advertising claims. Kids Mighty Immunity is a dietary supplement in gummy form that contains vitamin C from a standardized extract of acerola cherry, vitamin D3, zinc, Wellmune™ baker's yeast beta glucan and elderberry juice powder. Olly provided a reasonable basis for the claims: (1) "formulated to help support little immune systems in the biggest way to help keep kids healthy and happy year-round"; (2) "Wellmune. These beta glucans support immune health by helping to promote built-in cellular defense mechanisms"; (3) "Elderberry. Respect your elders – this super food has been used for centuries to support the immune systems" and (4) "Zinc. An essential mineral that helps keep immune cells functioning in tip-top shape."

Olly appreciated the opportunity to participate in, and will continue to strongly support, the self-regulatory process.

**National Media Group
Neurocet**

Case # 6066 (3.17.17)

The Council for Responsible Nutrition (CRN) challenged express claims in direct-to-consumer advertising regarding the strength of pain relief, length of pain relief, and speed of pain relief experienced by Neurocet users. Health-related product efficacy claims should be supported by competent and reliable scientific evidence. Competent and reliable scientific evidence consists of human clinical trials that are methodologically sound and statistically significant to the 95% confidence level with results that translate into meaningful benefits for consumers that relate directly to the performance attributes promised by advertising. NAD concluded that National Media Group's evidence was insufficiently reliable to substantiate the claims that Neurocet "Lasted 26 times longer than 10 popular pain drugs," "Relief lasted 5 days after one dose," and "48 times stronger than morphine" and recommended that the claims be discontinued.

National Media Group did not provide competent and reliable evidence sufficient to substantiate its claim that "Neurocet helps you get rid of pain all over your body." National Media Group relied on research on all the ingredients in Neurocet, ApresFlex (a compound derived from *Boswellia serrata*), DLPA, and calcium fructoborate in support of its claim that Neurocet "helps you get rid of pain all over your body." The studies submitted in support of the claim included test population that were far too narrow to support the claim, as well as animal studies that did not support claims for products marketed to humans.

NAD further recommended that the unsupported claims that "Patients with the worst pain imaginable found relief in under an hour" and that Neurocet provided "Clinically Proven Results" be discontinued.

NAD determined that the quantified claims that “Stiffness plunged 60%, mobility improved 49% and pain fell 62%” and “Amazing 71.3% increase in flexibility and movement” were not a good fit for the support provided and recommended the claims be discontinued.

NAD recommended that National Media Group discontinue claims that implied Neurocet may be used to prevent, treat, and/or manage pain and medical conditions such as arthritis. National Media Group's claims were broader than the research cited could support. Claims that imply Neurocet treats arthritis and other medical conditions do not match the support provided. Advertisers must take care to make sure that the research relied on is relevant to the specific product being promoted and to the specific benefit being advertised to a particular audience.

National Media Group agreed to comply with NAD's recommendations.

Beauty Science Group, Inc.

Hair La Vie

Case # 6055 (2.21.17)

Beauty Science Group elected to permanently discontinue the following challenged claims: (1) All natural hair repair formula; (2) Repair and regrow hair; (3) Once the follicle is repaired, hair begins to grow; (4) Unbreakable hair stage; (5) Hair La Vie products can reverse or cure baldness; (6) In our latest consumer survey, 82% reported faster existing hair growth* (*Based on a consumer survey measuring customers' opinions and subjective experiences with Hair La Vie) (revised from the originally challenged “82% saw faster hair growth.”). In reliance on the advertiser's representation that the claims were permanently discontinued, NAD did not review these claims on their merits.

Beauty Science Group agreed to modify claims that its Hair La Vie dietary supplement was “Made in the USA,” that users would achieve “Healthier. Longer. Fuller” hair “Longer. Fuller. Faster.” The claim Beauty Science Group “Created Hair La Vie because I never wanted another woman to have to go through the insecurity and heartbreak with hair loss, thinning and damage” was also modified.

NAD recommended that Beauty Science Group modify the claim “The ingredients in Hair La Vie help promote existing hair growth” to state that the biotin in Hair La Vie helps promote existing hair growth. Brock Beauty, Inc. challenged the claim. In the studies presented, some of the test populations were not relevant, and the amounts of the ingredients administered in the studies did not match the amounts of the ingredients in the actual product. Also, Beauty Science Group merely presented an informal summary of studies. Such informal summaries generally do not impart enough information for NAD to properly evaluate whether the studies cited constitute competent and reliable scientific evidence. Beauty Science Group also relied on an opinion on biotin issued by the European Food Safety Authority (“EFSA”) which states that “biotin contributes to the maintenance of normal hair.” The EFSA opinion can support qualified claims. However, Hair La Vie contains a daily dose of 5000

micrograms or 5 mg of biotin, which is more than the minimum dose recommended by the EFSA to make a qualified claim regarding the role of biotin in maintaining existing hair growth.

NAD determined that a consumer use survey of 276 customers was not sufficiently reliable to support the challenged objective performance claims about Hair La Vie. A properly conducted consumer use survey requires certain standards and controls to ensure that the responses are free from bias (e.g., blinding, randomization), that there is a representative study population, and that there is proper validation of the results. Beauty Science Group failed to provide any information concerning the survey methodology or any controls that were used to ensure the reliability of the results. Only one out of the 12 questions in the questionnaire related to a subjective assessment, and the responses to most of the questions were inherently unreliable.

NAD further determined that Beauty Science Group failed to support the claim “Hair La Vie uses natural and safe ingredients. This product contains no fillers, harsh chemicals or artificial flavoring/coloring.” Brock Beauty argued that the claim implied that all of the ingredients in Hair La Vie were safe. Beauty Science Group did not submit any testing demonstrating that its products, or the ingredients therein, were safe, but argued that it was not claiming that its ingredients are 100% safe or that the product was proven to be safe. NAD rejected Beauty Science Group’s arguments in support of the claims. Nothing prevented Beauty Science Group from promoting the absence of certain chemicals and/or artificial flavoring/coloring.

NAD also recommended that Beauty Science Group, Inc. advise ConsumersSurvey.org that they cannot make unsupported claims, including through the use of testimonials, that the advertiser cannot itself substantiate and that the advertiser must clearly and conspicuously disclose the relationship between itself and ConsumersSurvey.org in order to be effective. Beauty Science Group has an affiliate marketing relationship with ConsumerSurvey.org. ConsumerSurvey.org has two webpages which feature Hair La Vie. Consumers are likely to weigh ConsumersSurvey.org’s recommendation of Hair La Vie differently if consumers have knowledge that ConsumerSurvey.org receives compensation for purchases of Hair La Vie from its website. Also, paid endorsements may not convey any express or implied claims that would be misleading if made directly by the advertiser. Because Beauty Science Group failed to support its claims that Hair La Vie grows thicker, stronger, or fuller hair, ConsumersSurvey.org could not make the unsupported claims.

Beauty Science Group agreed to comply with NAD’s recommendations.

UltraBotanica, LLC
UltraCur Dietary Supplements
Case # 6052 (2.1.17)

UltraBotanica provided a reasonable basis for its claim “Curcumin is extracted from Turmeric, a plant that has been studied for centuries for its medicinal properties. Curcumin has been widely studied for its antioxidant properties.” Europharma, Inc.

challenged online advertising for UltraBotanica's UltraCur dietary supplements. Standard curcumin is not well-absorbed, and typically people must consume many grams of curcumin to produce a detectable amount of curcumin in their blood plasma. The curcumin marketplace contains enhanced absorption curcumin products that have been formulated to improve the bioavailability of curcumin. However, Europharma claimed that UltraBotanica's absorption claims were extraordinary and unsupported. Both parties agreed that curcumin has been used as traditional medicine. Therefore, NAD determined that the advertiser had provided a reasonable basis for the challenged claim. However, UltraBotanica provided no evidence that UltraCur is more easily digested than prescription medications. Consequently, NAD recommended that the advertiser discontinue its claim, "Ease of digestion: UltraCur is easy to digest and won't upset your stomach like many prescription drugs."

NAD determined that UltraBotanica failed to provide a reasonable basis for its efficacy and performance claims made online for its UltraCur dietary supplements. Mouse studies submitted by UltraBotanica in support of its claims were insufficient to support any of its health-related, superior absorption claims. The mouse studies were not a reliable substitute to support claims of curcumin absorption performance in humans. Further, a human study, which consisted of 1-3 participants with wildly variable peak curcumin concentration results, was also insufficient to support the challenged claims.

NAD noted that any use of the mouse study by UltraBotanica in support of health-related claims for its UltraCur dietary supplements should be clearly and conspicuously qualified to expressly note that the data was obtained from mice, and there is no evidence that the results will be obtained in humans.

UltraBotanica agreed to comply with NAD's recommendations in its future advertising.

Jelly Belly Candy Company
Jelly Belly Sports Bean Energizing Jelly Beans
Case # 6048 (1.24.17)

Jelly Belly presented sufficient evidence to support the advertising claim that its Jelly Belly Sports Bean Energizing Jelly Beans were "Clinically proven to maximize sports performance, each bean is loaded with carbs for fuel, electrolytes to help maintain fluid balance and vitamins to optimize energy release and protect cells against oxidative damage." Establishment claims, such as "clinically proven" claims, are traditionally held to a high standard of scientific proof because they are, in essence, a promise that there is scientific evidence that "establishes" the truth of an advertiser's claims. The results of a study submitted by Jelly Belly showed that all of the carbohydrate supplement forms tested (sports beans, sports drink and gel) were equally effective in maintaining blood glucose levels during exercise and improving cycling time-trial performance as compared to water alone.

NAD further determined that the claim "Sports Beans Energizing Jelly Beans are formulated to help fuel the body during intense exercise" was supported.

NAD recommended that the claim that Jelly Belly sports beans are “Scientifically Formulated to Maximize Sports Performance” be discontinued. The target audience, endurance athletes, would reasonably interpret this claim to mean that the amounts of the highlighted ingredients have been proven to provide an optimal performance, i.e., a faster run and/or ride. Jelly Belly failed to submit any ingredient studies showing that the amounts of the ingredients in Jelly Belly Sports Bean Energizing Jelly Beans would confer a measurable or optimal performance benefit for endurance athletes.

Jelly Belly Candy Company will comply with NAD's recommendation to discontinue the claim “Scientifically Formulated to Maximize Sports Performance.”

Fit Products, LLC

FitTea

Case # 6042 (12.28.16)

Fit Products, LLC voluntarily discontinued advertising claims that its FitTea “boosts immunity” and “burns fat” as well as its modification of the claim “boosts metabolism” and NAD will treat these discontinued and modified claims, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply. NAD also appreciated voluntary modifications to social media posts republished on Fit Products' website, and will treat these modifications, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply. NAD also recommended that Fit Products discontinue its claims that FitTea “boosts energy” and “supports metabolism.”

Fit Products agreed to comply with NAD's recommendations.

Yukon Reyes Consulting, LLC

ProBrain Dietary Supplements

Case # 6031 (12.7.16)

The Council for Responsible Nutrition (CRN) requested that the NAD examine the advertising claims for Yukon Reyes Consulting's ProBrain supplements to determine if there is adequate substantiation to support its claims. During the pendency of this challenge, NAD noted that one of Yukon's websites became defunct, and a second website stopped selling ProBrain. As the ProBrain websites are no longer operational, this matter no longer warrants the expenditure of NAD's resources. NAD reserved the right to open a monitoring case should the challenged ProBrain claims (or similar ones) become active again in the future.

BioPharmX Inc.

Violet Iodine Breast Health Supplement

Case # 6021 (11.4.16)

After requesting substantiation for advertising claims made by BioPharmX Inc. for its Violet Iodine Breast Health dietary supplement, the National Advertising Division found

there was a reasonable basis for the claim that “Violet Iodine is designed for women with fibrocystic breast condition . . . who want to proactively take care of their health.” For health-related claims, competent and reliable scientific evidence is human clinical trials that are methodologically sound and statistically significant to the 95% confidence level, with results that translate into meaningful benefits for consumers that relate directly to the performance attributes promised by advertising. The studies submitted by BioPharm were sufficient to support the claim. However, BioPharm’s claims regarding “premenstrual breast discomfort” and “cyclic mastalgia” needed to better reflect that molecular iodine, in same dosage as that found in one Violet Iodine pill, had only been clinically “demonstrated” to provide relief to women with fibrocystic breast condition who are experiencing premenstrual symptoms.

NAD determined that BioPharmX provided a reasonable basis for the claim that “Violet tablets are different from other iodine supplements. Violet tablets are made with a unique, patented formulation that blends two iodine ingredients in a non-hormonal formulation. These two forms of iodine combine in the stomach to form molecular iodine.”

NAD determined that the claim “Molecular iodine is a form of iodine that has been demonstrated to reduce the symptoms of premenstrual breast discomfort. Molecular iodine has been demonstrated to help restore the natural, healthy balance of breast cells” does not overstate the performance capabilities of the product. However, NAD recommended that it be modified to more accurately state that “Molecular iodine is a form of iodine that has been demonstrated to reduce the symptoms of premenstrual breast discomfort associated with fibrocystic breast condition (FBC). Molecular iodine has been demonstrated to help restore the natural, healthy balance of breast cells.”

In reliance on BioPharmX’s representation that it has permanently discontinued its claims “What is the advantage of using Violet iodine over non-prescription pain relievers or nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, Tylenol, Motrin, Pamprin, Aleve and Advil? These drugs only mask the symptoms with fibrocystic breast condition whereas Violet iodine seeks to address the underlying cause of the symptoms”; and “Violet Iodine . . . is regulated by the US Food and Drug Administration . . .,” NAD did not review these claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

BioPharmX agreed to comply with NAD’s recommendations.

Princeton Nutrients, LLC

VitaPulse

Case # 6017 (11.3.16)

Princeton Nutrients voluntarily discontinued advertising claims for its VitaPulse dietary supplement. The advertising claimed that VitaPulse eased joint pain and stiffness, improved sleep and reduce anxiety, increased mental sharpness and clarity, reduced muscle ache and soreness, and increased metabolism. NAD did not review these

claims on their merits. Because Princeton indicated that it would continue to use testimonials that VitaPulse increased energy and provided support for its increased energy claims, NAD recommended that Princeton Nutrients discontinue testimonials which make those claims.

NAD appreciated the voluntary and permanent modification of the Princeton Nutrients website to include all product reviews received through the exclusive channel through which products can be purchased. Discontinuance of the practice of including only selected reviews on its website would be treated, for compliance purposes, as though NAD recommended its discontinuance and Princeton agreed to comply.

NAD recommended that Princeton Nutrients discontinue testimonials that Vita Pulse lowers blood pressure, reduces cholesterol, or increases energy. Consumer testimonials which make performance claims about the product must be substantiated in the same way that such claims would need to be substantiated if made directly by the advertiser. The support provided was insufficiently reliable to support the strong, health-related claims made in the testimonials.

Princeton agreed to comply with NAD's recommendations and thanks NAD for its efforts in self-regulating the advertising marketplace.

IsoSensuals

IsoSensuals TIGHT Vaginal Tightening Pills & Gel and CURVE Butt Enhancement Cream

Case # 6008 (10.6.16)

Rather than submitting substantiating evidence to support its Internet advertising claims for its TIGHT Vaginal Tightening Pills dietary supplements and gel and its CURVE Butt Enhancement Cream, IsoSensuals elected to permanently discontinue the challenged claims. In reliance on the representation that these claims had been permanently discontinued, NAD did not review the claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

IsoSensuals stated that the challenged claims have been permanently discontinued and will not be used in future advertising.

HFL Solutions, Inc.

Blood Sugar Optimizer Dietary Supplements

Case # 6000 (9.9.16)

The Council for Responsible Nutrition (CRN) challenged Internet advertising claims by HFL Solutions, Inc. for its Blood Sugar Optimizer dietary supplements. CRN was concerned that the claims may lead consumers to use the Blood Sugar Optimizer product to prevent, treat, and/or manage diabetes and other medical conditions rather than conventional medical treatment. HFL cited animal studies, in vitro studies, and human clinical trials on the ingredients in Blood Sugar Optimizer supplements to

support its claims. With the exception of a very qualified claim regarding chromium picolinate supplementation, the evidence did not provide a reasonable basis for the health-related performance claims. The evidence presented supported the following claims: "all natural ingredients -NO harmful drugs."; "provide[s] antioxidant protection."; "doctor formulated"; "I am a type 2 diabetic, and the herbs in this are listed in natural insulin assistants."; and "antioxidant protection." Each of the remaining claims at issue was not supported.

HFL Solutions agreed to comply with NAD's recommendations.

Nootrobox, Inc.

Advertising for Nootropics

Case # 5995 (8.30.16)

NAD requested substantiation for certain express performance and implied claims disseminated by Nootrobox in Internet advertising for its RISE™, SPRINT®, and YAWN™ dietary supplements, collectively referred to as "Nootropics." According to Nootrobox, "nootropic" is a descriptor which spans across all regulatory classifications of compounds with cognitive enhancing properties. While well-controlled human clinical studies on the specific product advertised are considered the most reliable form of evidence, an advertiser may also provide reliable evidence demonstrating that it is scientifically sound to extrapolate the conclusions drawn from other studies and data and apply them to the performance claimed for the advertised product. Nootrobox argued that studies on each of the ingredients, collectively, supported the challenged product performance claims. However, there was no reliable evidence demonstrating that the product's formulation produced the benefits that each ingredient produced on its own. NAD therefore recommended that all of the challenged product performance claims for RISE™, SPRINT® and YAWN™ be discontinued.

NAD determined that Nootrobox provided a reasonable basis for ingredient claims relating to the ability of caffeine in its SPRINT dietary supplement to increase focus and mental clarity and the melatonin in its YAWN dietary supplement to provide sleep benefits. NAD recommended that the claim "Nutrients for your brain" should be discontinued or modified to reflect that SPRINT contains caffeine which has been found to increase focus and mental clarity. NAD also recommended that the claim "Upgrade your brain" be discontinued.

NAD recommended that Nootrobox customer testimonials be discontinued. Consumer testimonials about the performance of an advertised product or service are interpreted as representing that the product or service is effective for the purpose depicted in the advertisement. Therefore, the advertiser must possess and rely upon adequate substantiation including, when appropriate, competent and reliable scientific evidence to support such claims made through endorsements in the same manner the advertiser would be required to do if it had made the representation directly, i.e., without using endorsements. The challenged testimonials about the increased energy and mental focus attributed to "nootropics" were not supported by

any competent and reliable evidence demonstrating the product themselves confer the claimed benefits.

Nootrobox agreed to comply with NAD's recommendations.

DSE Healthcare, LLC
Prelief Dietary Supplements
Case # 5991 (8.22.16)

NAD requested substantiation for internet advertising claims made by DSE Healthcare, LLC for its Prelief dietary supplements. Prelief, a dietary supplement intended to remove the acid from foods that may irritate the bladder, consists solely of calcium glycerophosphate (CGP). DSE argued that taking Prelief before or during food consumption reduces the acidity of food, thereby reducing the overall acidic contribution to the stomach. Advertising for Prelief made heartburn relief claims, and comparative claims regarding the difference in its mechanism of action between Prelief and over-the-counter H2 blockers and PPIs (e.g., Prilosec). DSE also claimed that Prelief is as bioavailable as the calcium in milk, citing CGP's widespread use as a calcium fortifier in foods, including testing of its bioavailability in infant formula prescribed to infants with very low birth weight. However, there was insufficient evidence to support the claims that Prelief completely removes or neutralizes acid entirely. Nothing precluded DSE from making modified claims more carefully tailored to its acid reduction evidence (for example, "Prelief reduces acids from foods and beverages" or "Prelief helps neutralize the acid in offending foods."). Also, given the efficacy testing of Prelief on ninety-nine food products and beverages, NAD determined there was a reasonable basis for its claim "acid reduction – how much Prelief to take per serving," and the accompanying chart of quantified acid reduction claims of a variety of foods and beverages. In light of the fact that CGP does not occur in nature and was created specifically to help neutralize the acids in food, NAD determined that DSE provided a reasonable basis for its claim that Prelief is "designed" to help reduce acids in food.

DSE's website contains numerous testimonials offering people's personal experiences using Prelief to treat and/or prevent their interstitial cystitis symptoms. Advertisers 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. NAD was concerned about testimonial claims from a person who was bedridden with her interstitial cystitis pain until discovering Prelief. There was no evidence demonstrating that the expected symptom cessation is so significant that a bedridden person would be able, within a single day, to return to a hectic schedule as claimed in the testimonial.

DSE Healthcare, LLC agreed to comply with NAD's recommendations.

Legacy Labs, LLC
Cognitive Dietary Supplements
Case # 5982 (8.3.16)

Legacy voluntarily and permanently discontinued advertising claims for its dietary supplement challenged by competitor Kyowa Hakko Bio., Inc. In response to the NAD proceedings, Legacy Labs notified NAD that the company became defunct in March 2016, its website is no longer operational, and it has no intention of reintroducing the supplement to the market. Legacy Labs also reached out to third party websites to help remove the challenged claims from the marketplace.

Legacy Labs agreed to comply with NAD's decision.

Mars Incorporated
CocoaVia Cocoa Extract Dietary Supplement
Case # 5980 (7.29.16)

The Council for Responsible Nutrition (CRN) challenged claims made by Mars Inc. for its CocoaVia Cocoa Extract dietary supplement. NAD had requested substantiation for print advertising and website claims made by Mars Incorporated for its CocoaVia Cocoa Extract dietary supplement. CocoaVia was advertised as “scientifically proven to promote a healthy heart by supporting healthy blood flow, helping firefighters, or anyone, maintain who they are for years to come.” Based on Mars’ written representation that it permanently discontinued the Firefighter print ad claims and references to “stress” in connection with cocoa flavanols prior to the date of the complaint, NAD administratively closed its inquiry as to those claims.

NAD recommended that Mars modify its comparative advertising claim to make clearer the basis of that comparison. Mars advertised that “CocoaVia daily cocoa extract supplement delivers the highest concentration of cocoa flavanols.” NAD was concerned that a consumer could reasonably take away the message that CocoaVia supplements provide the highest concentration of cocoa flavanols versus untested cocoa products. This message was not supported by the evidence in the record. The claims should make clear that the comparison was between the CocoaVia and the representative chocolate confectionary products depicted in the chart, and not against all products marketed to contain cocoa flavanol content.

NAD further recommended that the claim that CocoaVia was “scientifically proven to promote a healthy heart by supporting healthy blood flow” be modified to clearly reflect that “studies indicate that cocoa flavanols promote a healthy heart by supporting healthy blood flow.”

Mars agreed to take the NAD decision into account in developing future advertising for CocoaVia® products.

Moon Juice

Moon Juice Action Dust and Brain Dust Dietary Supplements

Case # 5976 (7.16.16)

Moon Juice elected to permanently discontinue advertising claims for its Moon Juice Action Dust and Brain Dust dietary supplements challenged by the National Advertising Division.

Moon Juice thanked NAD for its expeditious resolution of this matter.

Prevention Pharmaceuticals, Inc.

Omax3 Ultra Pure Dietary Supplement

Case # 5966 (7.6.16)

Prevention was unable to support advertising of its Omax Ultra Pure omega-3 dietary supplement as superior to competing products. NAD determined that the studies and supporting evidence submitted by Prevention were insufficient to support the claims. Omax3 contains DHA, an ingredient may raise LDL levels, rendering it less likely that Omax3 contributed to the LDL lowering effects experienced by study participants. The studies did not show that Omax3 reduced inflammation in humans. Finally, there was no evidence demonstrating that the nine competitors selected for purity testing represented a substantial portion of the omega-3 supplement market. An advertiser may have reasonable basis for a market superiority claim if it has tested itself against a substantial portion of competing products available in the U.S. marketplace, but that evidence was not present here.

NAD also noted that nothing in the decision precluded Prevention from truthfully and accurately touting its well-documented low levels of impurities in a manner that is carefully tailored to its evidence.

Prevention agreed to comply with NAD's decision.

Advanced Nutritional Innovations, Inc.

ionDEFENDER Dietary Supplements

Case # 5959 (5.25.16)

The Council for Responsible Nutrition (CRN) challenged Advanced Nutritional Innovations, Inc.'s (ANI) advertising claims for its ionDEFENDER dietary supplement. ANI argued that ionDEFENDER elevated superoxide dismutase (SOD) antioxidant levels in the body, which increased cells antioxidant capacity and inherently protected the body from damaging ionizing radiation and a variety of undesirable health conditions. ANI submitted in vitro and animal studies, some of which support the assertion that the biological mechanism of action of SOD is that it catalyzes reactive oxygen species. Animal and in vitro studies are of limited value in predicting the effect of a substance on a human health condition. While many of the submitted review articles held out hope for identifying therapeutic uses for antioxidant enzymes, scientific consensus for the "protect your body" benefits of SOD supplementation was absent. NAD

determined that the medical literature reviews, *in vitro* and animal studies, failed to provide a reasonable basis for any of the advertiser's damage/disease protection, aging, radiation and hang-over claims.

NAD also determined that Advanced Nutritional Innovations, Inc. provided a reasonable basis for its claim that "SOD plays the primary role, transforming the most dangerous free radicals, the superoxide radicals, into ions that are less reactive. These are further transformed by Catalase and glutathione peroxidase," as it was simply descriptive of mechanism of actions of these antioxidants.

Advanced Nutritional Innovation, Inc. agreed to comply with NAD's recommendations for any future ionDEFENDER advertising.

Mega-T, LLC

Mega-T Green Tea Fat Burning Supplement

Case # 5952 (5.11.16)

In reliance on Mega-T's representation that it permanently discontinued a series of challenged claims, NAD did not review the claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

NAD determined that Mega-T may truthfully claim that its Mega-T Green Tea Fat Burning Supplement contains the probiotic lactobacillus coagulans.

NAD also determined that short-term studies and evidence submitted by Mega-T did not support the broad, unqualified "boosts metabolism" claim. The studies showed that subjects whose diets are supplemented with a combination of green tea catechins and caffeine (in amounts similar to that in Mega-T) experience statistically significant, short-term increases in energy expenditure. However, none of the studies measured metabolism for more than one day. It was unclear whether long-term habitual use would elicit the same metabolism boosting results. Nothing prevented Mega-T from making a carefully tailored claim that more closely matches the evidence in the record, namely the short-term nature of the recorded metabolism benefit.

NAD further determined that Mega-T failed to support the claim that its dietary supplement "burns fat" because the claim conveyed a broader message regarding the physical benefit a consumer would expect from the supplement than was supported by the studies in the record. Much of the evidence presented in support of this claim relates to short-term increases in fat oxidation after taking a green tea with caffeine supplement. While NAD acknowledged the promising nature of this research, evidence "not inconsistent with the possibility" of an impact does not provide a reasonable basis for the claim that taking Mega-T supplements actually "burns fat" off of American consumers' bodies. Therefore, the "burns fat" claim overstated the level of efficacy. Accordingly, NAD recommended that the claim be discontinued.

Mega-T, LLC agreed to comply with NAD's recommendations.

NuScience Corporation
Cellfood Dietary Supplements
Case # 5931 (2.17.16)

As part of NAD's routine monitoring program, NAD requested substantiation for advertising claims made in print advertising for NuScience Corporation's Cellfood Dietary Supplements. In light of NuScience's representation that the challenged claims had been permanently discontinued prior to the commencement of this inquiry and will not be used in future advertising, NAD administratively closed this matter.

Silver Star Brand
JuniorSlim™
Case # 5918 (1.11.16)

Silver Star Brands elected to permanently discontinue advertising claims and testimonials for its JuniorSlim dietary supplement. NAD requested substantiation for certain claims made by Silver Star. NAD did not review the claims on their merit and will treat the claims for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

Silver Star Brands voluntarily elected to discontinue the product.

BrainFire
BrainFire
Case # 5914 (12.23.15)

BrainFire voluntarily undertook to permanently discontinue advertising claims challenged by the Council for Responsible Nutrition. NAD did not review these claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

BrainFire stated that the advertising at issue has been voluntarily and permanently discontinued.

Vital G-Netics/SSB Holdings, Inc.
FlexSure® Restorative Joint Health Dietary Supplement
Case # 5912 (12.21.15)

NAD requested substantiation for Internet and product packaging advertising claims for Vital's FlexSure Restorative Joint Health dietary supplement. FlexSure is advertised as promoting joint health by balancing the genetic forces that are involved in tissue breakdown and tissue growth. The gold standard of competent and reliable scientific evidence for health claims are methodologically sound human clinical trials on the advertised product itself. Vital G-Netics submitted five studies to support the claims, but only one was found to be sufficiently reliable.

NAD determined that Vital G-Netics/SSB Holdings provided a reasonable basis for its claim that clinical trials showed that its dietary supplement users had significant increases in joint comfort, mobility, and flexibility, but recommended that the claims be modified to reflect that they were based on a single study.

NAD further determined that Vital G-Netics/SSB Holdings, Inc. failed to support advertising claims concerning the safety of its dietary supplement FlexSure Restorative Joint Health because there was no long-term study that specifically looks at the safety of FlexSure. A narrower claim that FlexSure was shown to be safe would be permissible if Vital G-Netics disclosed that this claim is based on the results of a single, 8-week study.

NAD also recommended that Vital G-Netics/SSB Holdings, Inc. discontinue advertising for its dietary supplement that touted it as “chondroitin free.” The advertising conveyed an unsupported superiority message over glucosamine chondroitin. Vital G-Netics could make a carefully-tailored “chondroitin free” claim that did not convey a superior efficacy message.

Vital G-Netics agreed to take the NAD decision into consideration and modify its marketing claims to comply with the decision. Vital G-Netics appreciated the opportunity to participate in the self-regulatory process.

Neuracel.com, LLC
Neuracel Nerve Pain Relief

Case # 5907 (12.7.15)

The Council for Responsible Nutrition (CRN) inquired into Neuracel.com's print advertising and product packaging claims for its Neuracel Nerve Pain Relief. The challenged claims, which appeared on a website owned and operated by Neuracel.com's prior owner, claimed that Neuracel eliminated nerve pain and that consumers taking prescription medication to relieve nerve pain could achieve better results by taking Neuracel. Health-related claims must be supported by competent and reliable scientific evidence, specifically a randomized, double blind, placebo-controlled trial design. Neuracel submitted one animal study on one compound from one plant that comprised Neuracel's proprietary formula as support for the challenged claims. Generally, animal studies are insufficient to support claims relating to the performance of a product, or its ingredients, in humans. Because Neuracel failed to provide any competent and reliable scientific evidence to support its challenged performance claims, NAD recommended that they be discontinued.

NAD determined that Neuracel.com failed to provide reliable support for its testimonials concerning its dietary supplement, and a proposed disclaimer was insufficient. A website owned and operated by Neuracel's prior owner featured testimonials proclaiming substantial, if not total, relief from various types of nerve pain, with some individuals stating that they took Neuracel instead of prescription pain medications or that they no longer take their prescription pain medications after taking Neuracel. However, there was no reliable supporting evidence demonstrating that consumers achieved substantial or total nerve pain relief by taking Neuracel. Neuracel

agreed to modify its advertising by including a disclaimer which refers to a DSHEA disclaimer that FDA has not evaluated the challenged claims, that consumers should consult with their physicians before taking Neuracel, and that the results depicted in the testimonials may not be achieved by all consumers. Neuracel's proposed disclosure was insufficient because the challenged claims it would qualify, which promise relief from nerve pain, were unsupported.

Neuracel appreciated NAD's review of claims and agreed to take NAD's recommendations into account in future advertising.

Brock Beauty, Inc.
Hairfinity Hair Vitamin
Case # 5904 (11.23.15)

Lifes2Good, Inc. challenged claims made by Brock Beauty, Inc. that its Hairfinity Hair Vitamin dietary supplement was "Clinically proven to decrease number of hairs shed and increase hair growth," "Our B-Vitamin complex nourishes and supports a healthy scalp and hair growth," and "The exclusive Capilsana complex provides a special sulfur and 18 amino acids that encourage healthy hair growth." The claims were permanently discontinued, and NAD did not review those versions of the claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

NAD found that a study relied upon as support for Brock's claims for its hair growth supplement did not constitute competent and reliable scientific evidence. NAD recommended that Brock Beauty discontinue its claims that, "Results of a 2013 study show that Hairfinity decreases the number of hairs shed and increase[s] hair growth," and that the product "promote[s] faster growing, longer, thicker, stronger hair."

NAD also determined that Brock was unable to support claims that its dietary supplement "supports," "nourishes," or "encourages healthy hair growth." The claims conveyed a broad message that the dietary supplement stimulated hair growth that consumers would not otherwise experience. However, Brock Beauty was unable to show that the supplement supported existing hair growth from within. NAD noted that Brock Beauty would be able to support a more limited claim regarding the role that the biotin in Hairfinity plays in "supporting" consumers' existing hair growth and maintenance."

NAD further determined that the claims "Healthy hair from the inside out" and "formulated with hair specific nutrients to nourish your hair from the INSIDE OUT" were supported by the evidence. Brock Beauty's claim that its product promotes "more vibrant hair" was puffery not requiring substantiation.

Brock Beauty agreed to comply with NAD's recommendations.

New Nordic U.S.A., Inc.
Skin Care™ Collagen Filler
Case # 5901 (11.9.15)

New Nordic U.S.A., Inc. was unable to support wrinkle reduction and anti-aging claims made for its Skin Care Collagen Filler dietary supplement in print advertising and on product packaging. NAD inquired about New Nordic's express performance and implied claims. Although New Nordic was conducting clinical testing on its product, it had not done so before disseminating the claims. Given the absence of any competent and reliable scientific evidence to support the challenged product performance claims, NAD recommended that the claims be discontinued.

New Nordic will take NAD's recommendations into account in its future advertising and ensure that it complies with any relevant regulatory authority.

EOK Marketing, LLC, d/b/a Marine Essentials
OmegaFlex Dietary Supplements
Case # 5892 (10.8.15)

Instead of submitting substantiating evidence, EOK Marketing, LLC d/b/a Marine Essentials elected to permanently discontinue all of the challenged claims and testimonials, for its OmegaFlex dietary supplements. In reliance on the representation that these claims had been permanently discontinued, NAD did not review these claims on their merits.

EOK Marketing, LLC, agreed to comply with NAD's recommendations.

Advanced Orthomolecular Research, Inc.
UTI Cleanse, Now with Cranberry, Dietary Supplements
Case # 5891 (10.8.15)

Because the intended target audience of Advanced Orthomolecular Research, Inc.'s advertising for its UTI Cleanse was Canadian, NAD closed its inquiry into that advertising. Advanced Orthomolecular Research refused to participate in the NAD process because it claimed that it was a Canadian business that promoted and sold UTI Cleanse dietary supplements in Canada. Some U.S. consumers may purchase UTI Cleanse via Amazon. Advanced Orthomolecular Research stated that U.S. consumers received a bottle with the disease claim "helps prevent urinary tract infections" purged from the label. Also, Advanced Orthomolecular Research agreed to contact the third-party seller and urge it to use a picture of the U.S. bottle without the claim. NAD concluded that this advertising was not "national in character" as defined by NAD's procedures, and administratively closed the matter. However, NAD remained concerned with the advertiser's continued assertion that it had evidence to support its broad, unqualified, powerful disease claims that its UTI Cleanse supplements can cure acute urinary tract infections and prevent their reoccurrence.

Lang Pharma Nutrition, Inc.
CVS Hair Nourishing Supplement
Case # 5881 (9.2.15)

NAD recommended that Lang discontinue unsupported comparative performance claims. Lifes2Good, LLC, manufacturer of Viviscal dietary supplements, challenged Lang's advertisements for its CVS Hair Nourishing dietary supplements. Both hair growth supplements contain marine blends of shark and mollusk powder, as well as biotin, zinc, vitamin C, horsetail extract, keratin and iron. Both supplements also contain 450 mg of a marine sourced collagen compound, both ostensibly comprised of shark and mollusk powder. By reviewing the Supplement Facts panel, the products appear to be almost identical. Life2Good argued that Lang's "compare to Viviscal" claim was an unfair comparison because it implies that the two products' efficacy was similar, a claim not supported by sufficient evidence. Viviscal has been clinically tested for efficacy, while CVS has not. Therefore, there was no evidence to support the implied message that the CVS and Viviscal brands were similar in type, composition, and efficacy. It was likely that consumers would have difficulty assessing the effectiveness of Viviscal product.

NAD recommended that Lang discontinue unsupported claims that its CVS Hair Nourishing dietary supplement was "drug-free nutrient formula for thinning hair." Claims based on the ingredients in a product must be supported by underlying studies with the same ingredients in the same dosage, formulation, and route of administration as the products at issue. Lang's two randomized, placebo-controlled studies on horsetail extract could not be extrapolated to the population at large. Also, it was not clear if the horsetail extract in the studies were similar in dosage and formulation as the horsetail in CVS. Further, the clinical end points of those studies were hair strength, breakage, and smoothness rather than hair growth or thickness.

NAD further recommended that Lang discontinue its claim that its CVS Hair Nourishing dietary supplement was "scientifically formulated to support existing hair growth" because it conveyed the unsupported message that the product as a whole had been tested for efficacy. Lang submitted European Food and Safety Authority scientific opinions and various journal articles that concluded that the current scientific consensus was that nutrients such as biotin, zinc, iron, vitamin C, collagen, and chondroitin contribute to the maintenance of normal hair and hair growth. Lang failed to demonstrate that the supplementation of these nutrients in the absence of a deficiency would promote hair growth beyond a person's natural capacity. NAD also recommended discontinuation of the unqualified claim that CVS "supports existing hair growth from within."

NAD determined that a modified claim that the ingredients in its CVS Hair Nourishing Supplement "supports existing hair growth from within" was supported because it was expressly limited to the physiological role of the nutrients found in CVS in hair growth and maintenance. For similar reasons, NAD found that Lang provided a reasonable basis for its claim "by providing nutrients this unique supplement supports existing hair."

NAD further determined that the product name “Hair Nourishing Supplement” was expressly truthful and not likely to mislead consumers. Absent extrinsic evidence that consumers have been confused or misled, NAD is reluctant to require an advertiser to change the name of a product simply because a challenger speculates that it might be misleading. The claim “hair nourishing supplement” was literally true in that the product contained many nutrients associated with normal hair maintenance and growth, and there was no evidence of actual consumer confusion.

NAD also determined that a claim that CVS Hair Nourishing Supplement was “scientifically formulated for beautiful hair” was puffery and did not require substantiation.

Instead of submitting substantiating evidence, Lang elected to permanently discontinue “scientifically formulated to support existing hair growth for women with thinning hair,” “by providing marine source collagen and chondroitin, as well as biotin and zinc, this unique supplement supports optimal conditions for growth of existing hair” and a chart comparing the amounts of nutrients in Viviscal and CVS Hair Nourishing Supplements. Therefore, NAD did not review these claims on their merits. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

Lang agreed to comply with NAD's recommendations.

Clarion Brands, LLC
Lipo-Flavonoid® Plus
Case # 5879 (8.31.15)

NAD determined that the claim “Lipo-Flavonoid Plus has been used and evaluated in clinical settings for over 50 years” and similar claims were supported.

NAD recommended that an advertiser discontinue claims, including a testimonial, which reasonably conveyed the unsupported message that Clarion Brands, LLC's Lipo-Flavonoid Plus substantially reduced or eliminated tinnitus and the symptoms of Ménière's Disease. NAD had several concerns about the reliability of studies submitted by Clarion to support the efficacy claims. While some of the studies and articles spoke favorably about bioflavonoid supplementation to treat tinnitus and Ménière's Disease, many did not.

NAD determined that Clarion's “doctor recommended” claim that its Lipo-Flavonoid Plus was supported but should be discontinued or modified. “Doctor recommended” claims require well-conducted, random, and statistically significant survey of doctors showing that a substantial percentage of doctors recommend the product, and their conclusions should be based on their actual experience and what they actually recommend in their daily practice. Clarion supported the claim using the results of two, independent surveys of ear, nose, and throat doctors. NAD determined that one survey was not sufficiently reliable to support the challenged claim. The other survey, which was adequate, indicated that the surveyed doctors recommended dietary

supplements to patients suffering from tinnitus or Ménière's disease and that only 1.2 percent recommend specific named brands other than Lipo-Flavonoid Plus. However, the doctors were not asked, nor did they indicate, that Lipo-Flavonoid Plus was recommended because it substantially reduced or eliminated tinnitus and the symptoms of Ménière's Disease. NAD recommended that Clarion discontinue the reference to "for relief of ringing in the ears" in connection with the "#1 Ear Doctor Recommended" claim or modify the claim to make clearer that it is recommended as an adjunct therapy for tinnitus and Ménière's Disease.

Clarion will appeal NAD's adverse findings to the NARB.

NARB (#208 – 1.14.16) recommended that Clarion discontinue claims that reasonably imply that Lipo-Flavonoid Plus provides significant or complete relief for ringing of the ears. This decision did not preclude Clarion from truthfully advertising that Lipo-Flavonoid Plus may provide relief for some people who suffer from tinnitus.

The panel also recommended that Clarion discontinue its claim that Lipo-Flavonoid Plus is the #1 recommendation of doctors for relief of ringing in the ears. This decision did not preclude Clarion from truthfully advertising that Lipo-Flavonoid Plus is the #1 recommendation of doctors as an adjunct therapy for tinnitus or Ménière's Disease.

Clarion agreed to comply with the NARB's findings.

Novartis Consumer Health, Inc.
Benefiber

Case # 5873 (8.13.15)

Novartis failed to provide a reasonable basis for its claim that Benefiber "helps maintain regularity." The Procter & Gamble Company, maker of competing dietary supplement and laxative product, Metamucil, challenged television and print advertising for Benefiber. The claim at issue is a "structure/function" claim, which is defined as a claim about the effect of a dietary supplement on the normal structure or function of the human body, or how it maintains such structure or function. Many of the studies presented by Novartis were primarily focused on testing the ability of humans to tolerate large doses of fiber without discomfort or negative side effects, which were not relevant to the truthfulness and accuracy of the claim at issue. None of the studies showed that supplementation of a healthy American adult population with 9 grams/day of wheat dextrin, the daily dosage for Benefiber, or an equivalent fiber provided any measurable improvement along any of the various markers that would indicate an improvement in "regularity." Therefore, NAD recommended that the claim be discontinued.

Novartis respectfully disagreed with the NAD's conclusions on the scientific issues, and will appeal to the NARB to request that the claim at issue be allowed based on the scientific evidence. However, Novartis appreciated the opportunity to participate in the NAD self-regulatory process.

NARB (#206 – 12.17.15) recommended that Novartis/GSK discontinue the challenged claim that Benefiber helps maintain regularity. This decision did not preclude Novartis/GSK from truthfully advertising the importance of fiber in the human diet and/or other digestive health benefits provided by Benefiber. Novartis agreed to comply with the NARB's determination.

Arthri-D, LLC

Arthri-D3

Case # 5871 (7.31.15)

Arthri-D voluntarily discontinued testimonials and endorsements challenged by the Council for Responsible Nutrition (CRN). CRN was concerned that claims made in the 30-minute infomercial and on the website, through the use of endorsements and testimonials were unsupported. CRN contended that the challenged testimonials attest to dramatic improvements in joint and arthritis pain relief after a few weeks on Arthri-D3. NAD did not review these claims on their merits based on the discontinuance. The voluntarily discontinued claims will be treated, for compliance purposes, as though NAD recommended their discontinuance and the advertiser agreed to comply.

Arthri-D was not required to change the name of its dietary supplement "Arthri-D3." The Council for Responsible Nutrition (CRN) argued that the product name expressly conveyed the message that Arthri-D3 treats arthritis and asked NAD recommend that the name "Arthri-D3" be discontinued. NAD shared CRN's concern that the name "Arthri-D3" when used in conjunction with testimonials related to relief from arthritis pain might convey the misleading message that "Arthri-D3" immediately and completely relieves arthritis pain. Given the voluntary discontinuation of the testimonials relating to relief from arthritis pain, NAD did not review the messages implied by the testimonials in combination with the product name, "Arthri-D3."

Despite Arthri-D's disagreement with some aspects of CRN's concerns, it appreciates the role CRN plays in the marketing of dietary supplements and will endeavor to consider the issues outlined by CRN and NAD in any potential future advertisements.

Great Health Works, Inc.

Omega XL Dietary Supplements

Case # 5870 (7.28.15)

Great Health Works, Inc. failed to support claims that its dietary supplement was a breakthrough treatment. Omega XL is a supplement that provides omega-3 fatty acids, including EHA and DHA, that Great Health Works advertised as a breakthrough treatment that relieved joint pain due to inflammation, was more potent and contains more free fatty acids than omega-3 oils sourced from fish, and was free from harmful toxins and PCBs. Great Health submitted clinical trials on the efficacy of Omega XL, an expert report on the scientific literature, a compositional report analyzing the amounts of free fatty acids of Omega XL versus the six leading fish oil brands, and a report of the level of toxins, PCBs and heavy metals found in a sample of Omega XL. NAD

determined that Great Health provided a reasonable basis for its claim that Omega XL was supported by “over thirty years of clinical research,” with regard to joint pain, but Great Health could not support the claim that its product was a “breakthrough secret.”

NAD recommended that Great Health discontinue its claim that “Omega XL Makes It Easy For You.” NAD also determined that a study submitted by Great Health provided a reasonable basis for the remainder of the claim “Get Back What Joint Pain And Inflammation Are Limiting You From Doing Because Omega XL Works.”

NAD recommended that Great Health discontinue its unqualified claim “with none of the common side effects associated with standard fish oil, krill and salmon oils.” Great Health did, however, provide a reasonable basis for a claim that Omega XL does not cause “fish burps” and that “Omega XL “contains up to 22 times more omega-3 free fatty acids than regular fish oil!” NAD also determined the claim that “Omega XL, smaller, yet MORE POTENT than regular fish oil” was supported by the evidence. However, given how many different types of fish oils are on the market, NAD recommended that Great Health clearly and conspicuously disclose the basis of comparison.

Great Health Works, Inc. agreed to permanently discontinue testimonials for its Omega XL Dietary Supplement, an action that NAD determined was necessary and appropriate.

Great HealthWorks agreed to comply with NAD’s recommendations.

Motherlove Herbal Company

More Milk Plus

Case # 5865 (7.14.15)

Motherlove Herbal Company failed to support the claim that its More Milk Plus herbal lactation supplement was an “effective herbal formula designed to quickly increase breast milk for breastfeeding mothers.” NAD requested substantiation for certain performance claims and testimonials made by Motherlove on its website and in print advertising. Motherlove provided numerous reference articles and monographs on More Milk Plus’s ingredients and their properties, but there was no actual product testing in the record. Even if the ingredients in More Milk Plus were recognized by some ethnobotanical sources as traditionally used for lactation as a galactagogue, the amount of these ingredients in a daily dosage of More Milk Plus did not reach the minimum dosage amount for use as a galactagogue according to Motherlove’s own expert opinion summary questionnaire. NAD also recommended Motherlove discontinue consumer testimonials regarding the performance benefits of More Milk Plus.

Motherlove Herbal Company was unable to support the claim that “Fenugreek is a highly recommended herb to quickly increase breast milk supply” given the lack of evidence that the dosage of Fenugreek in the product provides any therapeutic

benefit. The amount of Fenugreek in the daily dose of More Milk Plus was less than the dosage amount found to be efficacious in the studies cited by Motherlove. Also, Motherlove did not provide competent and reliable scientific evidence to show that the sub-therapeutic dose of Fenugreek actually increased breast milk supply.

Motherlove agreed to comply with NAD's recommendations.

Aspire Beverage Company

Aspire Sports Drink

Case # 5861 (7. 8.15)

Aspire Beverage Company (ABC) was unable to support testimonial claims that its ASPIRE sports drink would contribute to consumers' health and sports performance. Stokely-Van Camp, Inc., which makes Gatorade sports drinks, challenged ABC's advertising claims that ASPIRE was the "clear choice for health and performance" and "designed to improve the health and performance of athletes." ABC submitted numerous studies related to sugar and its harmful effects, specifically the harm associated with drinking excessive amounts of sugar-sweetened sports drinks. However, there was no evidence that ASPIRE enhanced health or that it enhanced performance, and the research on sugar and general health outcomes was not sufficient to substantiate the broad claims. ABC provided no support as to sugar's impact on athletic performance, or evidence of the health impact of reducing the comparative quantities of sugar found in Gatorade and ASPIRE. Also, evidence that ASPIRE was free from artificial flavors and food coloring did not support claims that its product contributed to better health and performance. ABC noted it had revised this language from "clear choice for better health and performance" to "clear choice for health and performance," but did not agree to make any additional changes based on NAD's recommendations.

NAD also recommended that ABC discontinue the unsupported claims that competitor Stokely-Van Camp, Inc.'s Gatorade sports drink contained "empty calories" or provides "extra sugar." ABC argued that research showed sports drinks contained too much sugar for most consumers and unnecessary artificial ingredients, and that sports drinks contribute to increased consumption of added sugar and excess calorie intake. Although excess sugar can be harmful to some consumers' health, ABC failed to show that Gatorade contained "empty calories" or provides "extra sugar" when used as energy replacement during vigorous exercise. ABC also failed to demonstrate the energy replacement benefits of ASPIRE. To the extent ABC seeks to compare the sugar and/or sodium content of ASPIRE to Gatorade, it must make clear the differences between the products in terms of energy benefits and electrolyte replacement.

NAD further determined that ABC was unable to support advertising that ASPIRE was a "natural sports drink." Natural claims are supported if "nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food." ABC did not provide any evidence that all of its ingredients were

natural. ABC was not barred from claiming that its products are naturally sweetened or naturally flavored or include specific natural ingredients.

NAD also recommended that ABC discontinue unqualified claims that Gatorade contained high fructose corn syrup and discontinue comparing nutrient information on different size servings of competitor sports drinks and discontinue any claim which implies that Gatorade shows nutrient information on a serving size that is less than the container size of its drinks.

Because ABC will not discontinue its unqualified claim that ASPIRE is a “natural sports drink,” NAD referred this case to the attention of the appropriate government agency for possible enforcement action.

Inspired Nutrition, LLC
Ultimate Bio-Fibrin Dietary Supplements
Case # 5857 (6.18.15)

Inspired Nutrition, LLC voluntarily and permanently discontinued advertising claims for its Ultimate Bio-Fibrin dietary supplement challenged by the Council for Responsible Nutrition.

Inspired Nutrition, LLC, agrees to take NAD's recommendations into account in future advertising.

Institute For Vibrant Living
Alleviate
Case # 5852 (6.10.15)

NAD determined that IVL provided a reasonable basis for its claim that “Salicin, a derivative of white willow bark, has been used for centuries to reduce pain and swelling in arthritic joints” and for a claim that the vitamin C in Alleviate supported “antioxidant protection against free radical damage.” The Alleviate formula was never clinically tested and IVL only submitted studies on the ingredients in Alleviate. Only studies that reached statistical significance against a placebo group on ingredients that matched the dosage, formulation, and route of administration as the ingredients in Alleviate were admissible. NAD determined that the studies supported claims that the ingredients in Alleviate may relieve pain in the knee and back caused by inflammation.

NAD further determined that IVL did not have a reasonable basis for any claim about the efficacy of Alleviate. NAD explained that Alleviate formula was never clinically tested and IVL only submitted studies on the ingredients in Alleviate. NAD only considered studies that reached statistical significance against a placebo group on ingredients that matched the dosage, formulation, and route of administration as the ingredients in Alleviate. Most of the studies submitted by IVL were not sufficiently reliable to support its advertising claims. The ingredient studies that were considered by NAD were directed to joint pain in the knees and back, and could not support IVL's

pain relief claims for other areas such as shoulders, elbows, and hands. Therefore, any claims not directed to the benefits of the ingredients in Alleviate for joint and pain in the back or knees were unsupported and must be discontinued or modified.

IVL appreciated the NAD's input and agreed to comply with NAD's recommendations.

Health Solutions, LLC
PhytoZon Supplements
Case # 5850 (6.5.15)

Health Solutions, LLC voluntarily and permanently discontinued advertising challenged by the Council for Responsible Nutrition. The many claims for its dietary supplement PhytoZon included: "Forget Pain Today;" "Doctor Approved - Rediscover Your Youth and Vitality;" "Results You Can Experience Immediately;" "The National Advertising Division of the Council of Better Business Bureaus, which monitors "truth in advertising" found that this compound was, '...a revolutionary solution, a breakthrough, all natural treatment in joint pain that does what no other products have done before,' that it '...actually helps alleviate Arthritis symptoms and increases flexibility and mobility' and that it may help '...in as fast as 7 days;" among others.

Health Solutions, LLC, agreed to take NAD's recommendations into account in future advertising.

Silver Star Brands, Inc.
Native Remedies® A+ TestCalmer™
Case # 5840 (5.5.15)

The Council for Responsible Nutrition (CRN) challenged performance claims and testimonials made by Silver Star for its Native Remedies® A+ TestCalmer™ dietary supplement on its website. Silver Star recently acquired the assets of Native Remedies, the manufacturer of Native Remedies® A+ TestCalmer™. After reviewing the Native Remedies line or products, it ceased selling A+ Test Calmer and is in the process of removing all marketing and promotional materials related to A+ Test Calmer. Discontinuation of the claims was necessary and proper given the lack of supporting evidence in the record.

Silver Star Brands accepted NAD's decision in its entirety and agrees to discontinue the advertising.

All Health Supplement Systems, LLC
Big "C" Dietary Supplements
Case # 5837 (4.24.15)

The Council for Responsible Nutrition (CRN), which expanded the NAD's review of advertising claims for dietary supplements, challenged All Health Supplement Systems, LLC's claims that its supplement was "the most advanced product to help keep you your body stay in favorable conditions so that it may not get this terrible disease;"

“Research the 16 ingredients, they all have shown different positive results in battling cancer in various lab studies and may help. In combination, this is ground breaking;” “As many as 70% of known causes of cancers are avoidable and are related to diet and lifestyle;” and that the supplement could prevent, treat or manage cancer. All Health stated that the challenged claims would be permanently discontinued. NAD appreciated the voluntarily discontinuation of the challenged claims, which necessary and appropriate.

All Health Supplement Systems, LLC, agreed to take NAD's recommendations into account in future advertising.

lovate Health Sciences International, Inc.

Six Star Whey Protein Plus

Case # 5831 (4.14.15)

lovate provided a reasonable basis for advertising claims made about the performance of its dietary supplement. The Council for Responsible Nutrition (CRN) challenged lovate's advertising and labeling for its Six Star Whey Protein Plus dietary supplement powder, which combined whey protein and creatine monohydrate. lovate claimed Six Star was “scientifically shown to build 70% more muscle”; “Test subjects gained 4x the muscle”; “Six Star® Whey Protein Plus is enhanced with core ingredients clinically shown to build more muscle and strength than whey protein alone”; and “Scientifically Shown to be 70% Better than Regular Whey.” In support of the claims, lovate submitted a clinical trial on two of the ingredients in Six Star Whey Protein Plus in which participants taking supplement powder formulation that was substantially similar to the Six Star product formulation gained more lean muscle than those taking only whey protein or a placebo. The labeling included language that sufficiently qualified the superiority claims because it disclosed that the ingredients in the product – and not the Six Star product itself – was tested, and allowed consumers to determine for themselves whether the study results were meaningful to them.

NAD recommended that lovate clearly, conspicuously, and in close proximity to its print claim “scientifically shown to be 70% better than regular whey” include the qualifying language that its claim is based on ingredient testing and also include the relative amounts of weight gained in the whey and whey-creatine groups.

NAD determined that lovate's study provided a reasonable basis for its claims that Six Star Whey Protein Plus “boosts strength & supports recovery” and “loaded with micro-filtered whey proteins, fast-absorbing BCAAs and glutamine to help you recover from your workout.” The claims were monadic and did not promise a specific level of performance. Also, the claims described, but did not overstate, the well-known and documented muscular strength and recovery effects of the ingredients of Six Star® Whey Protein Plus.

NAD further determined that lovate provided a reasonable basis for the challenged consumer testimonials and that in these instances no “generally expected results” disclosures were necessary.

lovate appreciated NAD's careful review of the issues presented in this challenge and will consider NAD's recommendations regarding product disclosures in future Six Star advertising.

SlimGenics, LLC
SlimGenics Weight-Loss Clinic
Case # 5807 (2.3.15)

SlimGenics provided a reasonable basis for its claim that SlimGenics is an "individualized, step-by-step nutritional plan that gives you the framework to eat the right foods at the right times, resulting in rapid weight-loss." SlimGenic's STEP program incorporated healthy eating habits with individualized nutritional plans that included dietary supplements, and one-on-one counseling. However, NAD recommended that SlimGenics omit an express or implied claim that consumers can expect to lose weight rapidly. Given the myriad weight-loss programs making scientifically impossible claims, a consumer could reasonably be confused about how long weight-loss can take, and that "rapid weight-loss" could mean a much shorter timeframe than the one to two pounds a week STEP program users typically experienced.

NAD also recommended that SlimGenics modify its testimonials to include qualifying language clearly disclosing that the weight loss obtained by clients making the testimonials was not typical of what consumers can generally expect to achieve. Competing weight reduction program Minnesota Weight Control, Inc. challenged SlimGenic's testimonials claim promoting generalized weight loss ranging from 20 to 295 pounds. SlimGenics modified its testimonials to include this disclosure prior to the issuance of this decision, an action that NAD determined was necessary and proper.

NAD further recommended that SlimGenics discontinue unsupported testimonial claims "... taught me how to keep the weight off for good" and "I... learned how to keep the weight off for good." The Federal Trade Commission and National Institutes of Health have cautioned advertisers against making claims of permanent weight loss. The advertiser failed to submit any competent and reliable scientific regarding whether the SlimGenics STEP program had resulted in long-term weight-loss.

SlimGenics permanently discontinued its claims: "Lose up to 3-5 pounds a week; "Lose up to 20 pounds in the first 30 days;" "Metabolizer herbs "boost the metabolism and aid in cleansing and detoxifying the body and its systems;" "Metabolizer herbs result in: more repaid weight loss; increased energy for work and exercise; decreased hunger sensations;" "I was amazed at how fast the weight came off and I was never hungry," an action NAD determined was necessary and appropriate given the lack of supporting evidence in the record.

SlimGenics thanked the NAD for its careful review of the matter, and have already made all of the changes recommended by NAD and agreed to take its recommendations into account with future advertising.

Natural Factors, Inc.

CurcuminRich Turmeric Root Extract with Theracurmin, Theracurmin-Pro 300, Theracurmin-Pro 600

Case # 5804 (1.26.15)

Europharma, Inc. challenged Natural Factor's advertising for its Theracurmin line of curcumin dietary supplements, arguing that consumers will not receive 100 mg of curcumin when taking Theracurmin as instructed based on results of a study. In previous cases involving curcumin, NAD has noted that curcumin may provide some health benefits, but is not well-absorbed or utilized by the human body. NAD recommended that the advertiser modify its claims that Theracurmin is "the most absorbable curcumin on the market," "clinically proven as the most bioavailable curcumin," "number one absorbed form of curcumin," "combining the use of natural emulsifiers to form a colloidal suspension had tremendously increased curcumin's bioavailability, significantly increasing blood levels of curcumin many times that of other preparations, including so-called enhanced forms of curcumin," to clearly and conspicuously limit them to the market data reflected in the SPINS report, i.e., the market comprised of the natural health and other specialty stores.

NAD further recommended that Natural Factors discontinue its claim that "Theracurmin increase curcumin levels in a linear and dose-dependent manner, bypassing previous limits to curcumin supplementation to achieve unparalleled blood levels of curcumin," because when Theracurmin, Meriva, and BCM-95 are taken in consumer-relevant amounts, the resulting blood levels of curcumin are essentially the same.

Natural Factors agreed to take the NAD's recommendations into consideration in its advertising.

Lifes2good, Inc.

Viviscal

Case # 5794 (12.22.15)

Lifes2good, Inc.'s print advertising and statements made on its website that its Viviscal dietary supplement was "clinically proven" to be effective were sufficiently supported.

Viviscal is an oral marine protein supplement designed to promote hair growth in consumers suffering from temporary thinning hair. NAD determined that four clinical studies provided by Lifes2good provided a reasonable basis for the claim that Viviscal was "clinically proven answer to thicker, fuller hair." The studies demonstrated that Viviscal-treated subjects perceived improvements in the thickness and fullness of their hair, significant increases in the vellus hair width of Viviscal-treated subjects compared to placebo, and a decrease in total shed hairs. NAD also found that Lifes2good supported the claim, "Viviscal is grounded in over 20 years of continuous research and

development. The efficacy of Viviscal vitamins for hair growth is supported by 7 clinical studies."

NAD determined that Lifes2Good was unable to support its claim that "91% of women noticed thicker hair" after using its Viviscal dietary supplement. The claim was based on a study which asked subjects to complete a self-evaluation and quality of life questionnaire. A reasonable consumer takeaway from such a specifically quantified claim was that a well-controlled study was performed and supported this claim. Another reasonable consumer takeaway from this claim is that 91% of women experienced noticeably thicker hair. Study participants taking a dietary supplement to promote hair growth may perceive that their hair is thicker, even when it is not. More women in the study perceived thicker hair than experienced an increase hair count in the tested area. Additionally, of the 92% of women noticing thicker hair, 43% noticed only a slight improvement in hair thickness. Therefore, NAD recommended that Lifes2Good discontinue the claim.

Lifes2Good agreed to comply with NAD's recommendations.

ADD-Care, LLC

ADD-Care Dietary Supplements

Case # 5785 (11.12.14)

ADD-Care, LLC was unable to provide reliable and competent scientific evidence to support claims made about its dietary supplement. The Council for Responsible Nutrition (CRN) challenged claims made by ADDcare on product labeling and on its website that its ADD-care® dietary supplement could treats symptoms of ADD/ADHD. ADD-care provided SPECT brain scan imaging of four subjects, taking scans without any stimulant, after taking ADD-care, and after taking the participant's prescription stimulant medication. However, the individual case studies and SPECT scan images could not substitute for competent and reliable scientific evidence. NAD recommended that ADD-care discontinue claims that the supplement improved focus, clarity, and alertness and relieved symptoms of hyperactivity, impulsiveness, inattention, forgetfulness, anxiety, as well as claims that it relieves "symptoms consistent with ADD and ADHD." ADD-care also failed to support the claims that ADD-care is safe and does not have any side-effects be discontinued as well. Finally, NAD recommended that ADD-care discontinue using any testimonials making unsupported claims related to ADD-care.

ADD-care, LLC will take into consideration NAD's decision as it reviews current and future advertising and labeling for the product.

LifeCaps Nutraceuticals, LLC

LifeCaps

Case # 5784 (11.6.14)

NAD recommended that LifeCaps Nutraceuticals, LLC discontinue all of its efficacy and performance claims for its dietary supplement. The Council for Responsible

Nutrition (CRN) challenged several Internet advertising claims disseminated by LifeCaps for its LifeCaps life-saving "survival pills." LifeCaps dietary supplement was for use in an emergency, to help curb appetite and provide the body with certain vitamins and nutrients to sustain life, on a short-term basis until real food can be consumed. LifeCaps failed to offer any clinical testing on its product that could be readily verified to support the claims.

LifeCaps agreed to comply with NAD's recommendations.

iMNAatural.com

Garcinia Cambogia Powder with 50% HCA Dietary Supplements

Case # 5777 (10.24.14)

NAD closed its inquiry into iMNAatural.com's advertising of its Garcinia Cambogia Powder with 50% HCA dietary supplements after iMNAatural.com discontinued the advertising. NAD had requested substantiation for Internet advertising claims that "Some of the possible health benefits of Garcinia Cambogia [is that it]... fights... [the] ebola virus." NAD appreciated the advertiser's participation in the self-regulatory process and its assurance that it would permanently discontinue the challenged claims. NAD deemed this action necessary and appropriate given the lack of any supporting evidence in the record.

Neogenis, LLC

Neo40 Daily dietary supplements

Case # 5770 (10.7.14)

CRN challenged certain advertising claims disseminated by Neogenis for its Neo40 Daily dietary supplement. The advertiser claimed that the physiology of nitric oxide (NO) in healthy individuals' bodies could be reproduced in individuals taking Neo40 Daily supplements. Neogenis produced as evidence a paper by Dr. Nathan Bryan which referred to a study by Janet Zand in Nutrition Research and also served as the basis for substantiating the advertiser's claims.

NAD determined that Neogenis provided a reasonable basis for its claims that NO is known primarily for maintaining normal blood pressure and blood flow, the inner lining of blood vessels use NO to signal vasodilation resulting in increasing blood flow and oxygen delivery, and the effects of NO are widespread throughout the body. However, NAD concluded that Neogenis did not produce competent and reliable evidence to support its claims that Neo40 Daily is (1) proven to help the body naturally increase its NO levels; (2) helps maintain healthy blood pressure; (3) helps support triglycerides; (4) helps maintain circulation; (5) is proven to help the body naturally increase its NO level which helps support sexual function; and (6) is proven to help support workout endurance.

Neogenis' case study and abstract failed to meet the criteria for competent and reliable scientific evidence. Consequently, NAD recommended that Neogenis discontinue those advertising claims.

Neogenis declined to abide by NAD's conclusions and appealed NAD's findings to the NARB.

NARB (#199 – 3.3.15) made the following determination:

The panel recommends that Neogenis discontinue the challenged claim that Neo40 Daily is proven to help the body naturally increase its nitric oxide levels. This does not preclude Neogenis from making truthful claims that Neo40 may help the body increase its nitric oxide levels.

The panel recommends that Neogenis discontinue the challenged claims that Neo40 Daily helps maintain healthy blood pressure and helps support blood pressure. This does not preclude Neogenis from making truthful claims that Neo40 Daily may help support healthy blood pressure and/or that preliminary studies indicate that Neo40 Daily may reduce blood pressure in certain consumers.

The panel recommends that Neogenis discontinue the challenged claim that Neo40 Daily helps maintain circulation. This does not preclude Neogenis from making truthful claims that Neo40 Daily may help support or maintain circulation.

The panel recommends that Neogenis discontinue the challenged claim that Neo40 Daily is proven to help the body naturally increase its nitric oxide level, which helps support Triglycerides. This does preclude Neogenis from making truthful claims that Neo40 Daily may help support Triglyceride levels.

The panel recommends that Neogenis discontinue the challenged claim that Neo40 Daily is proven to help the body naturally increase its nitric oxide level, which helps support energy levels, workout endurance, and sexual function. This does not preclude Neogenis from making truthful claims that (a) nitric oxide may support energy levels and workout endurance, and/or (b) Neo40 Daily has been shown to help support workout endurance in a small clinical trial involving female cyclists.

Neogenesis agreed to comply with NARB's determinations.

Cerebral Success

SmartX Premium Brain Supplement, Now with Cognizin.

Case # 5761 (9.10.14)

Cerebral Success failed to produce competent and reliable scientific evidence to support its product performance claims for SmartX Premium Brain Supplement, Now with Cognizin in a challenge before NAD.

Advertisers must demonstrate that a product performs the function promised or provides the benefit claimed in the advertisement. Cerebral Success submitted studies on the various ingredients found in SmartX, but did not provide any evidence that the SmartX product itself, or any particular formulation or variation of the product, had

ever been scientifically tested. NAD disagreed with Cerebral Success that studies on the ingredients provided sufficient support for the SmartX product claims. Therefore, the NAD recommended that the advertising be discontinued. NAD found that Cerebral Success provided a reasonable basis for claims regarding the benefits of the ingredients in its SmartX Premium Brain Supplement, Now with Cognizin.

However, in the absence of competent and reliable scientific evidence, NAD recommended that Cerebral Success discontinue its specific claims that L-Theanine “works to balance out the harsher effects of caffeine,” that Huperzine A “has been proven useful in improving short term memory as well as preventing long term memory loss as a result of aging,” and that L-Tyrosine supports “an increased feeling of well-being” and “has an antioxidant effect, which helps protect cell membranes from damage caused by free radicals.” There was also no credible scientific evidence to support the claims regarding Bacopin, Vinpocetine, Phosphatidylserine, Glucuronolactone, Schisandrin A, L-Glutamine, and B-Vitamins. NAD recommended that the claims that the ingredients contained within SmartX “are intended to strengthen brain cell walls,” “increase blood flow & oxygenation to the brain; stimulate protein synthesis; and boost production of acetylcholine” be discontinued as well.

NAD recommended that Cerebral Success discontinue the use of consumer testimonials in its advertising for its dietary supplement. The testimonials contained product performance claims that were not supported by independent competent and reliable scientific evidence.

Cerebral Success agreed to comply with NAD's recommendations.

Nature's Way Brands, LLC

Alive! Women's Energy, Alive! Men's Energy Alive Women's 50+ and Alive! Men's 50+ Multivitamins

Case # 5739 (7.1.14)

Bayer HealthCare, LLC challenged television, print, label, and internet claims made by Nature's Way for its Alive! Women's Energy, Alive! Men's Energy Alive Women's 50+ and Alive! Men's 50+ multivitamins. The claims implied that the Alive! Multivitamins would result in tangible, physical effect or cause an acute physical benefit.

Regarding Nature's Way's claim that the Alive! multivitamins are “made with 26 fruits and vegetables,” NAD reviewed the overall net impression of the advertising and packaging, and determined that a consumer could reasonably take away the message that the multivitamins contained the nutritional equivalence of 26 whole fruits and vegetables. From Nature's Way evidence, it was undisputed that the multivitamins were not equivalent to eating whole fruits and vegetables. Nature's Way claims that the multivitamins provide nutrition that consumers “can feel” and therefore literally provide palpable energy were not supported by the evidence. NAD recommended that Nature's Way discontinue its “Alive! Is nutrition you can feel”

claim. With respect to Nature's Way "superior potency" claim, NAD determined the claim was literally true since the multivitamins contained 100 percent of the daily value of 20 vitamins and minerals and therefore was not misleading.

Finally, NAD recommended Nature's Way discontinue its claim, "Get More from Your Multivitamin. A Lot More" because there was no evidence that Alive! Multivitamins provided more of a benefit than Bayer's One-A-Day multivitamins.

Nature's Way Brands stated that NAD broke with precedent in requiring an advertiser to establish an ingredient's specific nutritional benefits before being able to promote the presence of the ingredient through a "made with" claim. However, Nature's Way agreed to take NAD's decision into consideration in future advertising.

Bell Lifestyle Products
Virux Viral Infections #42
Case # 5738 (6.6.14)

The Council for Responsible Nutrition (CRN) challenged Bell Lifestyle's advertising claims for its Virux Viral Infections #42 dietary supplement, which appeared in a newspaper advertisement and on its website. The commercials expressly stated that the product would help with sexually transmitted diseases, herpes, cold sores, and influenza, and inhibited virus replication. The commercials allegedly implied that the product would less or kill cold, flu, and herpes viruses, and other infections. CRN maintained that Bell provided insufficient evidence to support its express claims and noted that the majority of the studies provided by Bell were review articles focusing on the broad use of medicinal plants and marine algae in various health applications, not all related to viral infections.

Bell explained that the products ingredients were formulated based on available scientific literature regarding each ingredient's demonstrated effect on viral infections. Bell stated that the print advertisement and testimonials have been permanently discontinued and it is in the process of revising its advertising to be consistent with what is allowed for dietary supplements by the Food and Drug Administration. Finally, Bell changed the name of the product and removed any reference to "viral infection."

NAD appreciated Bell's voluntary undertaking to permanently discontinue the express claims. NAD determined that, although Bell produced evidence of antiviral properties of certain individual ingredients, the evidence did not constitute competent and reliable scientific evidence to support performance claims that the product kills, prevents, or lessens the symptoms of herpes, flu, colds. NAD noted that Bell's revised claims are all geared towards promoting Virux as a supplement that will promote immune system health which are very different from the original claims of an "antiviral" product.

Lastly, NAD concluded that Bell's evidence provided a reasonable basis for its modified immune system support claims.

The advertiser agreed to comply with NAD's recommendations.

Pursuit of Research, LLC
Nutriveda Dietary Supplement
Case # 5725 (6.16.14)

NAD recommended that Pursuit of Research discontinue efficacy claims on its website and remove testimonials that were unsupported by reliable evidence. NourishLife, LLC, a manufacturer of Speech Nutrients, challenged Internet claims made by Pursuit of Research for its Nutriveda dietary supplements. The Pursuit of Research website contains numerous testimonials from purported users of Nutriveda. The website promises extraordinary results in the areas of speech and language development, motor skills, behavior, awareness, facial expressions and seizure control at a "nearly 100% success rate." Pursuit of Research introduced clinical trials, testimonial evidence from parents whose children supplement with Nutriveda, and animal studies. NAD found that Pursuit of Life was unable to present reliable supporting evidence for the challenged claims, and should discontinue its use of testimonials containing unsupported product efficacy claims. None of the articles submitted described studies that constituted competent and reliable evidence sufficient for claim support, nor did the animal studies support the health claims regarding the benefits of Nutriveda in children with autism, apraxia, traumatic brain injury, and global delays. Testimonials lack all of the elements of competent and reliable scientific evidence, and cannot be used to support health claims. It was not enough that the testimonials represented the honest opinion of the endorsers.

Pursuit of Research was required to properly disclose the association between it and a website that directly or indirectly promoted Pursuit of Research's dietary supplement. Pursuit of Research maintained "The Cherub Foundation" website, which hosts a blog and forums where parents can lend support and offer information with each other regarding their children's pressing health and neurological issues. NourishLife, LLC argued that the Cherub Foundation, which links to the Pursuit of Research, was used to sell Nutriveda without disclosing its close ties to the Pursuit of Research. NAD recommended that Pursuit of Research clearly and conspicuously disclose the material connection with the Cherub Foundation on the Cherub Foundation website, in a manner that is easy to notice, read and understand by readers of the website, as well as on each page or blog post.

PursuitofResearch.org agreed to comply with NAD's recommendations.

iSatori, Inc.
Energize – The All-Day Energy Pill
Case # 5714 (5.16.14)

iSatori supported, in part, claims concerning the NAD requested substantiation of iSatori's television commercials, packaging, and Internet advertising claim for its Energize – The All-Day Energy Pill dietary supplement. Although iSatori provided a reasonable basis for its claim that Energize was the "#1 Best Selling Energy Pill," the

NAD noted that iSatori must continually monitor the relevant sales data to ensure that the claim remains accurate. iSatori also provided a reasonable basis for its “no jitters” and “no bitter taste” claims based on the amount of caffeine in a dose of Energize and the product’s sweet coating. However, claims related to the ability of its product to provide energy for an extended period of time, such as “Just take two Energize tablets in the morning for all-day energy” and “8-Hour Efficacy Shown in Clinical Testing,” must be discontinued because iSatori’s testing did not support those claims.

iSatori appreciated the work of NAD to help the industry self-regulate advertising and would take NAD’s recommendations into account for future advertising.

Lutimax Nutraceuticals, LLC
Lutimax Pediatric Powder & Pediatric Powder with L-Theanine
Case # 5709 (5.7.14)

The Council for Responsible Nutrition challenged Internet advertising claims disseminated by Lutimax Nutraceuticals, LLC for its Lutimax Pediatric Powder & Pediatric Powder with L-Theanine dietary supplement. Lutimax Pediatric Powder, comprised of luteolin and rutin, was advertised as a patented proprietary formula clinically proven to help improve the quality of life in children with ASD by helping with speech improvement, emotional attachment, cognitive functions, coordination, behavior outbursts, attention span, intimacy, interaction and comprehension. The majority of the studies submitted by Lutimax were performed almost exclusively in vitro and on animals which do not constitute competent and reliable evidence for human health claims. The advertiser submitted one clinical study on children with ASD, but because the study was not a randomized, placebo-controlled, or blinded study, and used a different formulation and dosage of ingredients than that found in the Lutimax products, NAD determined that it was insufficient to support the advertiser’s claim. Therefore, NAD recommended that the advertiser discontinue all of the challenged claims. Nothing in the decision prevents Lutimax from making carefully qualified claims based on their in vitro and animal studies as long as the claims clearly and conspicuously disclose that they were based on in vitro and animal studies and did not convey the unsupported message that the results can be extrapolated to humans.

Lutimax Nutraceuticals disagreed with NAD’s conclusions, but in support of the self-regulatory process, agree to take NAD’s recommendations into account in future advertising.

Body Armor Nutrition, LLC
BODYARMOR® SuperDrink™
Case # 5703 (4.1.14)

NAD directed Body Armor Nutrition, LLC to discontinue statements made on its website and product labels. Body Armor claimed that BODYARMOR® SuperDrink™ was superior to Gatorade and other sports drinks on the market. In determining whether a monadic or comparative message is being conveyed by a “superior” claim, NAD considers two factors: (1) whether the claim contains a provable quantifiable attribute

and, if so, (2) whether the overall context in which the claim appears is monadic or comparative. NAD recommended that Body Armor either discontinue its "SUPERIOR NUTRITION + HYDRATION" in the contexts presented or sufficiently modify this claim so as to limit it to a strictly monadic context and avoid conveying any unsupported comparative message that its product provides superior nutrition and hydration in comparison to the leading sports drink. NAD further recommended that Body Armor either discontinue its "ELECTROLYTES: 2½X THE LEADING SPORTS DRINK" in the contexts presented here or sufficiently modify it to limit this claim to a monadic context and avoid any implication of superior hydration due to the inclusion of two and one-half times the electrolytes of the leading sports drink.

BODYARMOR believes that NAD should have rejected Gatorade's challenge and noted that it had created an entirely new website and updated its label, which rendered the claims moot. BODYARMOR will take NAD's recommendation into account and will endeavor to make clear that these are distinct claims that should not be read in combination.

Pharmavite, LLC

NatureMade Letter Vitamins, Fish Oil, Flaxseed Oil, CoQ1 and Diabetes Health Pack Supplements

Case # 5675 (1.14.14)

NAD requested substantiation for advertising claims made by Pharmavite, LLC for its NatureMade Letter Vitamins Fish Oil, Flaxseed Oil, CoQ1 and Diabetes Health Pack Supplements. NAD was concerned that the disclosure "US News and World Report – Pharmacy Times Survey" was not clear and conspicuous. Pharmavite stated that the television commercial had been permanently discontinued and agreed to present the disclosure more prominently in future advertising. NAD appreciated that Pharmavite voluntarily discontinued the challenged television commercial and promised to make its disclosures more prominent in future advertising.

Pharmavite was pleased that NAD decided to discontinue this matter and would abide by NAD's recommendations in future advertising.

Rainbow Light Nutritional Systems

Omega Skin & Mood Dietary Supplement

Case # 5671 (12.20.13)

NAD requested substantiation for advertising claims made by Rainbow Light Nutritional Systems for its Omega Skin & Mood dietary supplements. Omega Skin & Mood dietary supplements were removed from Rainbow Light's website and were not being promoted for sale. Rainbow Light assured NAD that the claims were permanently discontinued and that it had no intention of using the challenged claims in the future. Discontinuance was necessary and proper.

Trinity Sports Group, LLC

NeuroImpact

Case # 5666 (12.23.13)

TSG marketed its NeuroImpact dietary supplement as clinically proven to help the brain recover from contact sports. A “clinically proven” claim asserts to consumers that there is clinical proof that establishes the effectiveness of its product. NAD recommended that TSG discontinue its claims given the limited and emerging nature of the research on the ingredients in NeuroImpact. NAD determined that the NeuroImpact study did not rise to the level of competent and reliable scientific evidence required to support a clinically tested or proven claim. The methodology used made it impossible to discern what improvements resulted from NeuroImpact supplementation as opposed to the use of other supplements.

NAD recommended that TSG’s testimonials be discontinued. Advertisers may not make claims through consumer testimonials that could not be substantiated if made independently by the advertiser and that anecdotal evidence, based solely on the experiences of individual consumers, is insufficient to support product efficacy claims. Unless the advertiser can independently substantiate that the consumer endorser’s claims are typical of most users, the advertiser must clearly disclose the performance that consumers can typically expect, or the extent of the typicality of the endorser’s experience. TSG failed to provide a reasonable basis for its efficacy claims, and cannot support the claims made in the testimonials.

Although TSG disagreed with NAD’s conclusions, it agreed to take NAD’s recommendations into account in future advertising.

Prescription Vitamins, LLC.

Statinzyme Cholesterol Lowering Medication Supplement

Case # 5662 (12.13.2013)

NAD recommended that the advertiser discontinue its fish oil claims (“Fish Oil has been proven to lower cholesterol (LDL) and actually improve the performance of statins when taken together”; “A large clinical study (n>18,000) proved that the addition of fish oil to the statin regimen resulted in a statistically significant 19% reduction in the risk for major coronary events, defined as sudden cardiac death, fatal or non-fatal myocardial infarction, unstable angina, or the need for revascularization”) because the clinical trials that the advertiser relied upon to support its claims used different amounts, formulations and EPA/DHA ratios than that found in Statinzyme. For example, many of the studies that the advertiser submitted used highly purified EPA and there was no evidence in the record to suggest that the EPA in Statinzyme was highly purified. Another study that demonstrated a reduced risk for major coronary events used 1.8 grams of EPA, whereas Statinzyme contains 400 mg of DHA and 200 mg of EPA.

The advertiser agreed to comply with NAD’s recommendations.

XLEAR, LLC
Spry Dental Defense System
Case # 5661 (12.13.13)

NAD found that Xlear, LLC's advertising of its dental products was not supported by scientific evidence. NAD requested substantiation for Xlear's television and web advertising claims for its Spry Dental Defense System. Spry Dental Defense Systems consist of xylitol-added gums, mints, toothpastes, and mouthwashes for adults and children in various flavors. Xlear's evidence did not support its unqualified establishment claim that its products could "protect your teeth with scientifically-proven all-natural xylitol," and the NAD recommended that the statement be modified to better reflect its evidence by disclosing the (1) xylitol gum should be used in conjunction with fluoridated toothpaste, (2) xylitol gum is only recommended for healthy children at high risk for caries, ages five to sixteen years old and (3) adults who are at a high risk for caries. Only proven anti-caries benefit of xylitol mints is for healthy children five to sixteen-years old, at high risk for caries, that consume five to eight grams of xylitol per day. There was also insufficient evidence to support the claim that xylitol was a naturally-occurring sugar that could dramatically improve the health of teeth. Finally, NAD recommended that Xlear discontinue its claim that xylitol was "safe for all ages" or qualify that xylitol gum is safe for "neurologically healthy children 5 years and older who are willing and able to chew for an extended period," who should be supervised when chewing gum.

Xlear failed to submit an Advertiser's Statement indicating that it was either complying with NAD's recommendations or appealing the matter to the NARB. Therefore, NAD referred this matter to the appropriate regulatory authority.

HealthyLife Sciences, LLC
Healthe Trim Weight Loss Dietary Supplement
Case # 5641 (10.10.13)

Based on HealthyLife Sciences, LLC's inability to substantiate its advertising claims for its dietary supplement, NAD recommended that the challenged advertisements be discontinued and/or modified. The Council for Responsible Nutrition (CRN) challenged certain advertising claims disseminated by HealthyLife for its Healthe Trim dietary supplement. The advertiser submitted the Udani study, a randomized, placebo-controlled twelve week clinical trial. However, the study found that participants did not lose a significant amount of weight using the supplement. There was also a lack of statistical significance and/or clinical relevance between the control group and the Healthe Trim treatment group. Therefore, NAD recommended that the claims based on these studies be discontinued. NAD also recommended that the advertiser modify its safety claim that "Healthe Trim is perfectly safe" to include a reference to the length of time that the safety of Healthe Trim was studied and also that the safety study was conducted on participants that limited their caffeine intake to one serving a day or less. Such disclosures should be prominent and appear in close proximity to the safety claim.

Maximum Human Performance, LLC

MYO-X® Myostatin Inhibitor

Case # 5631 (9.11.13)

As part of its routine monitoring efforts, and in conjunction with NAD's initiative with the Council for Responsible Nutrition ("CRN") designed to expand NAD's review of advertising claims for dietary supplements, NAD requested substantiation for advertising claims made by MHP for its dietary supplement. MHP explained that the dietary supplement MYO-X is a beverage mix dietary supplement formulated to reduce the levels of a biological molecule called myostatin, which inhibits muscle differentiation and growth. NAD found MHP's evidence submitted in support of its advertising claims was insufficient support for the claim and recommended that they be discontinued.

Although MHP disagreed with the NAD's assessment of the underlying science and initial studies, it agreed to modify its claims to conform to NAD's decision and will develop claims based on the outcome of future clinical studies.

Wellnx Life Sciences, Inc.

NV Hollywood Weight-Loss Supplements

Case # 5629 (9.10.2013)

The evidence offered in support of advertising claims must mirror the claims in scope and nature.

NAD determined that the two clinical trials offered in support of the advertiser's weight-loss claims were methodologically sound in that both of the studies were randomized, double-blind, placebo-controlled studies that utilized the same dosage and form of the two active ingredients found in NV Hollywood. The study participants were obese women. However, there was no evidence in the record that the model in the advertising – who had not been obese when she began taking NV Hollywood – would achieve the same results in the same time frame. Further, the advertisement did not make reference to the diet and exercise changes that the study participants also underwent to achieve their weight-loss goals. Consequently, NAD recommended that advertiser discontinue its claims that NV Hollywood causes "fast" weight loss or has "incredible weight-loss power."

The advertiser agreed to comply with NAD's recommendations.

Supragenix, LLC

CB-1 Weight Gainer

Case # 5627 (9.9.13)

Dietary supplement maker Supragenix, LLC agreed to modify its advertising claims and develop claims based on the outcome of clinical studies on its formula. NAD requested substantiation for television and web advertising claims made by Supragenix for its CB-1 Weight Gainer dietary supplement product. Supragenix

provided an observational study and a variety of published studies as substantiation for its weight gain claims. NAD noted that the observational study did not meet the standard of competent and reliable evidence. NAD also determined that the published studies did not support the advertiser's efficacy claims. Accordingly, NAD recommended that Supragenix discontinue the unsupported weight gain claims.

NourishLife, LLC
SpeechNutrients Speak
Case # 5620 (8.8.13)

NourishLife, LLC offered to voluntarily and permanently discontinue its advertising claims for its line of dietary supplement products. 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. While the NAD asserted that the science behind the Speak product is emerging, 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.

NourishLife voluntarily discontinued certain claims and agreed to take NAD's recommendations into consideration in future marketing materials and advertising.

BPI Sports, LLC
Go Performance Pre-Training Powder
Case # 5614 (7.29.13)

NAD requested substantiation for certain advertising claims made by BPI Sports, LLC for its dietary supplement, Go Performance Pre-Training Powder. BPI Sports notified NAD that the claims at issue had been permanently discontinued, and that the labels for all the products at issue had been redesigned to eliminate the referenced claims. The advertiser emphasized that it does not intend to make such claims in future advertising.

BPI Sports, LLC
1 M.R. (One More Rep) Pre-Workout Powder
Case # 5613 (7.29.13)

NAD requested substantiation for certain advertising claims made by BPI Sports, LLC for its dietary supplement, 1 M.R. (One More Rep) Pre-Workout Powder. BPI notified NAD that the claims at issue had been permanently discontinued. It noted that the labels for the product had been redesigned to eliminate the referenced claims. The advertiser emphasized that it does not intend to make these claims in future advertising.

BPI SPORTS, LLC
SAAs Energy Dietary Supplement
Case # 5612 (7.29.13)

NAD requested substantiation for certain advertising claims made by BPI Sports, LLC for its dietary supplement, SAAs Energy. BPI notified NAD that the claims at issue had been permanently discontinued, and that the labels for the products had been redesigned to eliminate the claims.

DrFuhrman.com, Inc.
Immunotect
Case # 5611 (7.12.13)

NAD appreciated that, during the course of proceeding against a dietary supplement advertiser, the advertiser permanently discontinued the challenged claims from its website. NAD further concluded that the advertiser had provided a reasonable basis for its claim that "Immunotect is a unique blend of berries, herbs and ten mushroom concentrates designed to support several different aspects of immune function" and for the structure/function claims currently present on its web site as noted in NAD's decision.

New Nordic US, Inc.
Hair Volume
Case # 5606 (6.24.13)

Given the lack of reliable supporting evidence in the record, NAD recommended that New Nordic discontinue Internet and print advertisement that suggested the supplement was a unique innovation and reinvention of the old hair, skin and nail tablets, thousands of people had benefited from the product, it was the world's leading hair tablet with natural apple hair growth factor, was a new Scandinavian invention, and strengthened hair. NAD further recommended that the advertiser make it clear that the product simply "contains" apple extract. Lastly, NAD recommended that the unsupported testimonial be discontinued. The advertiser noted that while it felt it had some substantiation from the clinical studies of the supplement's ingredients, it intended to work with NAD to correctly advertise its product and would adhere to NAD's recommendations.

The Winning Combination, Inc.
Abrexin Weight Loss Supplement
Case # 5596 (5.30.13)

Upon receiving NAD's opening letter, a dietary supplement advertiser advised NAD that, prior to the commencement of the inquiry, it had voluntarily and permanently ceased all selling, marketing and advertising for the Abrexin weight loss product in the United States. Upon reviewing the advertiser's website and confirming that the product was only being sold at retail stores in Canada and was no longer being advertised in the United States, NAD determined that it did not have jurisdiction and administratively

closed the inquiry.

USPLabs, LLC
Jack3d Products

Case # 5576 (4.25.13)

NAD determined that challenged advertising claims for the dietary supplement Jack3d Micro, including “getting a pump as you drive to the gym,” could reasonably be interpreted as product performance claims and, given the absence of any product testing. NAD determined that these performance claims were not supported and recommended that they be discontinued. The advertiser had not provided information as to the dosage or formulation of ingredients in Jack3d Micro and, as a result, had not provided a reasonable basis to support ingredient claims regarding the benefits of those ingredients.

NAD also determined that the advertiser had not provided a reasonable basis for its “University Studied” claim, which appeared in conjunction with various performance claims for the product, and recommended that it be discontinued or modified to make clear the nature of the testing on Jack3d.

The advertiser agreed to comply with NAD's recommendations.

USPLabs, LLP
AP Dietary Supplement

Case # 5571 (3.9.13)

NAD appreciated an advertiser's voluntary agreement to add language to future advertisements for its AP dietary supplement to the effect that “AP has been designed and studied to be taken along with carbohydrates. If your nutrition regimen does not include carbohydrates, AP is not the product for you.” In order to avoid potential confusion from the claim “Ultimate Carb Solution” and the warning, “Don't eat carbs without it,” NAD recommended that the advertiser also add language to the effect that AP dietary supplement “may help” or is “designed to help” the body “better use” ingested carbohydrates.

NAD recommended that the advertiser's establishment claims that a “clinical study demonstrates first dose effectiveness” and that its AP dietary supplement was “University Studied,” be discontinued.

Lastly, NAD recommended that the advertiser modify its claim, “Award Winning Nutrient Partitioning Agent,” to clearly, conspicuously, and accurately disclose the years the award was given.

The advertiser stated that it would take NAD's recommendations into account in future advertising.

InterHealth Nutraceuticals, Inc.
Zychrome Dietary Supplement
Case # 5569 (4.8.2013)

Because the differences between patient groups using the competing dietary supplements Chromax and Zychrome did not reach statistical significance for any variable measured by a study, and also because the advertiser did not rely on head-to-head test results to support its comparative efficacy claims, NAD recommended that the advertiser discontinue its claims “the only form of chromium clinically shown to be twice as effective [or 1.4 times as effective] as chromium picolinate for managing insulin levels”; “2x more effective than chromium picolinate in improving insulin function”; and “2x more effective than chromium picolinate in managing insulin resistance.” However, to the extent that CDNC performed statistically significantly better than a placebo, nothing in this decision prevented the advertiser from making monadic claims.

NAD recommended that the advertiser discontinue its claims that Zychrome can “better manage glycemic parameters” and “manage metabolic health more effectively” because CDNC did not perform better to a statistically significant degree than a placebo at lowering glucose levels.

Given that Zychrome did not perform significantly better than chromium picolinate in the study, NAD recommended that the advertiser discontinue the claims “replace chromium picolinate with Zychrome to formulate more effective products for metabolic health”; “the most effective form of chromium to date”; “more effective than other chromium compounds for modulating glycemic parameters” and “Zychrome outperformed chromium picolinate on multiple key parameters tested.”

CDNC is a new form of chromium compound, a fact that the advertiser was free to tout. However, NAD recommended that the advertiser should modify its “next generation” claims to avoid conveying the message that Zychrome is superior to chromium picolinate.

NAD recommended that the advertiser discontinue its claims that “88% of diabetic educators prefer Zychrome over chromium picolinate for insulin management and over 70% would recommend Zychrome for insulin management over chromium picolinate if available on the market” because the survey was not sufficiently reliable to support a “diabetes educator” claim.

Finally, NAD noted that NAD's recommendations to discontinue certain claims applied to any medium in which these claims appeared—Internet, print advertising, radio, television, trade show publications, and business-to-business advertising.

The advertiser stated that it would modify advertising for Zychrome in accordance with the NAD's recommendations.

Matrix Initiatives, Inc.
Zicam Cold Remedy
Case # 5567 (3.25.13)

In light of Matrix's discontinuance, prior to challenge, of advertising for its "Cold Remedy *Plus*" as being more effective than other cold remedies, NAD administratively closed the proceeding with respect to that issue.

NAD recommended that all iterations of the advertiser's "clinically proven [to reduce the duration of a cold]" claims (in television, print, Internet and other advertising media), clearly and conspicuously disclose that this claim applies solely to its Zicam Rapid Melts, Chewables and Oral mist products and that its use be discontinued in advertising (including product packaging) featuring non-tested products (e.g. lozenges and Ultra Crystals) and non-cold remedy products.

NAD further concluded that, given the context in which the claims, "Pre-Cold Medicine" and "Go from Pre-Cold to No Cold Faster", consumers were unlikely to take away the message that Zicam Cold Remedy products provide a prophylactic benefit (that they will not contract a cold at all if they take the Zicam Cold Remedy product). However, NAD concluded that the claims, "Don't let a monster of a cold catch you" (and like claims), in the context in which they appear in print advertisements and on the advertiser's website, could reasonably be understood by consumers to mean either that they will not get a cold at all (full-blown or otherwise) or that Zicam will reduce the severity of a cold rather than simply the duration)—claims that were unsupported. Consequently, NAD recommended that these claims be discontinued. As concerns the challenged television commercial, however, NAD was satisfied that, in the context in which it is presented, the imagery of the "cold monster" was unlikely to convey the message that taking Zicam will reduce the severity of a cold.

NAD appreciated the advertiser's voluntary discontinuance of the language "concentrated formula" from its Zicam *ULTRA* advertising and product packaging, an action that NAD deemed warranted under the circumstances of this case. With this modification, NAD concluded that the evidence in the record that Zicam *ULTRA* products contain *more* of the active ingredient per dosage unit than their non-*ULTRA* counterparts, thereby requiring consumers to take fewer doses per day, and the fact that this language is not used in conjunction with any claims of increased efficacy, provided a reasonable basis for the advertiser's descriptor of these products as *ULTRA*. NAD further concluded that, absent consumer perception evidence to the contrary, the name "Zicam *ULTRA*", by itself, does not convey the message that these products are more effective than their non-*ULTRA* counterparts or other cold remedy products.

As for the advertiser's "#1 Pharmacist Recommended" and, the "#1 Pharmacist Recommended Brand" claims, NAD appreciated that the advertiser has removed its "#1 Pharmacist Recommended" seal from its current advertising, an action that NAD deemed necessary and proper. However, NAD recommended that the advertiser ensure that any use of "#1 Pharmacist Recommended" *language* clearly and conspicuously disclose that this rank was achieved in the "Homeopathic Cold

Products” category, so as to avoid the implication that Zicam achieved this position within the “Cold Remedy” category—a ranking held by the challenger’s Cold-EEZE product.

The advertiser stated that it would take NAD’s recommendations into account in future advertising.

Hello Life LLC

Synaptol

Case # 5562 (3.5.13)

NAD recommended that the advertiser of the homeopathic remedy product Synaptol discontinue unsupported claims that it treats or relieves ADD/ADHD symptoms. NAD further recommended that the advertiser discontinue its use of testimonials claiming that Synaptol treats ADD/ADHD symptoms or that it can be used as a replacement for or alternative to prescription treatments for ADD/ADHD.

The advertiser stated that it would take into consideration NAD’s decision in reviewing current and future advertising and labeling for the product.

Ampersand Industries, LLC

Trimedisyne Prenatal Vitamin

Case #5539 (1.2013)

After Ampersand Industries informed NAD that Trimedisyne Prenatal vitamin dietary supplement was no longer available for sale, NAD administratively closed the case. NAD appreciated the decision to discontinue the claims because the evidence was insufficient to support all of the challenged claims with the exception of three claims: (1) “Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that the evidence is inconsistent and not conclusive”; (2) “Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension;” and (3) “Three studies, including a large clinical trial, do not show that calcium supplements reduce the risk of preeclampsia during pregnancy. However, two other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of preeclampsia.”

Body Dynamics, Inc.

Mega Cleanse

Case #5538 (1.2013)

NAD recommended that the advertiser of the Mega Cleanse dietary supplement discontinue all challenged claims, modified claims and testimonials, including

“cleanse toxins from the liver, colon, kidneys, lymphatic system and blood” and help with weight loss.

The advertiser stated that it would take all of NAD's recommendations into account in future advertising.

Nature's Answer, LLC
Bio-Strath Food Supplement
Case #5536 (1.2013)

NAD recommended that the advertiser of the dietary supplement Bio-Strath discontinue all challenged claims for the product with the following exceptions: “Bio-Strath contains numerous strengthening nutrients needed by the human body for efficient performance and good health”; “This rejuvenating tonic has been used . . . for 47 years”; and “The deep intelligence of the body allows each cell to absorb only that which it needs for internal order and balance.”

The advertiser agreed to comply with NAD's recommendations.

Healthy Directions, LLC
Joint Advantage Gold Supplement
Case #5512 (October/November 2012)

NAD determined that a dietary supplement advertiser provided a reasonable basis for its claims that glucosamine in Joint Advantage Gold may “reduce joint pain,” “enhanced joint flexibility and mobility, less stiffness,” and “lubricate your joints and improve joint function.”

With regard to the advertiser's Australian and European herbal blends, NAD recommended that the advertiser discontinue the claim “the healing Australian and European herbal blends give your joints nourishment for greater mobility and comfort.” To the extent that the advertiser intends to limit to “traditional use” any claim related to these blends, NAD recommended that the advertiser refrain from any references implying that the Australian herbal blend was traditionally used by the Aboriginal people to relieve inflammation and joint discomfort. NAD did note however that these herbs do grow in Australia and NAD determined that the advertiser had a reasonable basis for referring to the blend as an Australian blend; however, wild rosella and aniseed myrtle were not traditionally used to reduce inflammation and the advertiser should exclude those herbs from any traditional use references. The European blend should exclude references to yucca and papaya because they do not traditionally grown in Europe.

NAD determined that the glucosamine studies provided by the advertiser were sufficiently reliable to provide a reasonable basis for its testimonial that “Joint Advantage Gold saved me! I thought I would never ride my Harley Davidson motorcycle again; now, I am back riding. It does wonders for my (pain). Thanks.” NAD recommended that other challenged claims and testimonials be

discontinued.

The advertiser stated that it intended to appeal NAD's conclusion regarding the Australian herbs in Joint Advantage Gold®, the relevant consumer testimonials, as well as its findings concerning the NEM studies and the claim that Joint Advantage Gold® can provide joint health benefits within seven days.

The NARB (#184 – 3.13.13) recommended that Healthy Directions discontinue claims that Joint Advantage Gold and/or its ingredients provide “fast relief,” reduce joint pain in as little as 7 days, and relieve joint discomfort/stiffness in as little as 7 days.

The panel also recommended that Healthy Directions discontinue claims that Joint Advantage Gold and/or its ingredients are formulated to work in every joint in the human body.

The panel further recommended that Healthy Directions discontinue its claim that wild rose and aniseed myrtle are herbs traditionally used in Australia to reduce inflammation or joint pain.

Finally, the panel recommended that Healthy Directions discontinue consumer testimonials that claim (a) Joint Advantage Gold is effective in eliminating joint pain, (b) Joint Advantage Gold is effective in eliminating or reducing pain during strenuous activities, (c) Joint Advantage Gold is effective after 4 days use, and (d) Joint Advantage Gold is effective for a particular age group unless Healthy Directions has reliable and competent scientific evidence to support the claim with respect to that age group.

The advertiser agreed to comply with the NARB's recommendations.

Abbott Nutrition
Ensure Clinical Strength
Case #5501 (9.2012)

With regard to Abbott's advertising claims that its dietary supplement Ensure Clinical Strength will help consumers “bounce back” when they are on the road to recovery, NAD determined that the message reasonably conveyed was simply that the product will help consumers recover from illness or injury, and that Abbott provided a reasonable basis for such claims. NAD also found Abbott's muscle benefit claims, such as “Ensure Clinical Strength has Revigor and 13 grams of protein to protect, preserve and promote muscle health” to be supported. However, NAD determined that it was not accurate to use the disclaimer that the studies were conducted in “healthy exercising adults” in connection with advertising for Ensure Clinical Strength and recommended that Abbott discontinue its use in this context.

With regard to the Ensure Clinical Strength product name and labeling, NAD concluded that consumers are likely to take away the message that Ensure Clinical Strength provides material and relevant benefits to a “clinical” population—a message that was truthful and accurate. Further, in the absence of a demonstration of

confusion regarding the designation “clinical strength,” NAD concluded that the product name and label Ensure Clinical Strength was unlikely to mislead consumers. Having determined that Abbott’s survey results were not sufficiently reliable to substantiate a quantified claim that Ensure is recommended over other brands of liquid nutritional supplements by a three-to-one ratio, NAD recommended that Abbott discontinue use of the claim “3 out of 4 doctors recommend the Ensure brand for extra nutrition.” Finally, with regard to the “#1 doctor recommended brand claim, NAD recommended that in order to avoid consumer confusion, Abbott modify the appearance of the seal, both on product labeling and in the Ensure Spot, such that the entire wording of the claim is sufficiently prominent, clear, and conspicuous to assure that consumers will understand that it applies to the Ensure brand of nutritional supplements rather than one particular product in the line.

The advertiser stated that it would take NAD’s recommendations into account in its advertising going forward.

Pharmapro, Inc.
Sterodrol Supplements
Case #5489 (8.2012)

NAD determined that a dietary supplement advertiser provided a reasonable basis in support of its claims that “Sterodrol is our new flagship and represents the next generation of Pharmapro Anabolics” and “Sterodrol delivers a whopping 1000mgs. per day of T. Alatus.” NAD recommended that advertiser discontinue its remaining performance claims that made repeated references and comparisons to anabolic steroids, including the originally challenged claims and proposed modifications. The advertiser stated that it agreed to make further revision to its advertising in light of NAD’s decision and to remove all performance claims from its marketing materials in any nationally circulated publications and on its website.

Interceuticals, Inc.
BetterWOMAN
Case #5485 (8.2012)

NAD found a dietary supplement advertiser’s evidence insufficient to support specific health claims that its BetterWOMAN product “Reduces Urinary Frequency,” “Reduces Urine Leakage,” “Improves Urinary Control,” and helps customers “Sleep Better Through a Night.” NAD recommended that the advertiser discontinue these claims and discontinue a “clinically tested” claim and testimonials claiming specific health results.

The advertiser stated that it accepted NAD’s recommendations and would take them into consideration in modifying future advertising.

Vital Pharmaceuticals, Inc., D/B/A VPX Redline
Medivin 100% Natural Liquid Vitamin & Mineral Delivery System
Case #5475 (7.2012)

NAD recommended that the advertiser of the dietary supplement Medivin discontinue its claims "It's not the amount you take, it's what you absorb and utilize" and "Top selling sports nutrition vitamin pack: released 8% riboflavin, 1.5% zinc and 0.75% calcium. Medivin: released 84% riboflavin, 96% zinc and 100% calcium" and refrain from implying that Medivin is more bioavailable than Animal Pak supplements.

The advertiser stated that it would comply with NAD's recommendations.

Euromedica, Inc.
PhosphOmega-3/Vectomega Supplements
Case #5474 (7.2012)

NAD recommended that a dietary supplement advertiser discontinue its claims that "in a recent clinical trial, subjects using PhosphOmega-3 experienced significant support in healthy total cholesterol, triglycerides and HDL levels. In addition, they reported significant improvement in several factors including improvement in concentration, mental vigor, quality of sleep, visual fatigue, long term and short term memory and physical recovery."

NAD recommended that the advertiser discontinue its claims that "PhosphOmega-3 is 100% sustainable and derived from 100% pure North Atlantic salmon."

With regard to the claims "scientific research has shown that omega-3 fatty acids bound to phospholipids have greatly enhanced bioavailability and stability than fatty acids on triglyceride carriers such as fish oil," NAD recommended that the advertiser discontinue its claim of "greatly enhanced bioavailability." However, nothing in this decision prevents the advertiser from making bioavailability claims that better reflect the state of the scientific inquiry into this issue; for example that small scale human studies and studies on infants and animals have demonstrated phospholipids to have a potential for greater bioavailability than triglycerides. NAD further determined that the advertiser had provided a reasonable basis for its claim that PhosphOmega-3 has "greatly enhanced stability."

NAD recommended that the advertiser discontinue the use of the word "heat" in its claim "its patented extraction process uses no heat, chemicals or solvents." The advertiser produced evidence sufficient to support its claim that it has a "patented extraction process."

NAD recommended that the advertiser discontinue its claim that "each batch of PhosphOmega-3 is tested and passes both US and European standards for purity; EuroMedica uses the highest sensitivity tests available to assure your patients' health

and safety." NAD determined that the advertiser had produced a reasonable basis for its claim "in fact, it would take over 150,000 PhosphOmega-3 tablets to be taken at one time to exceed the PCB safety level established by the State of California." The advertiser stated that it would take NAD's recommendations into account for future advertising claims for this product.

I-Health, Inc.

BrainStrong

Case # 5471 (7.2012)

NAD concluded that the evidence supported advertising claims that the dietary supplement BrainStrong "[s]upports brain development and function" in young children. NAD also determined that the advertiser supported other claims that appear in its print advertisement, including: "Now there's BrainStrong with life's DHA™. It's the safe and natural way to give your toddler's brain the DHA it needs"; "Provides an important brain nutrient lacking in most kids' diets"; "Contains the same brand of DHA found in infant formula"; "You nurtured his brain with DHA when he was just in a crib. Why stop now when he's expanding his territory?" NAD also determined that this print advertisement did not convey the implied message that "[a] child's brain will not develop and function well without DHA supplementation."

Lunada Biomedical, Inc.

Amberen

Case # 5466 (6.2012)

NAD determined that a voluntary undertaking by Lunada Biomedical to discontinue some challenged claims for its Amberen dietary supplement for menopausal women was necessary and appropriate—including claims that relief is "complete," "fast," that Amberen is an "all in one solution," that Amberen can achieve "balanced production and circulation of hormones throughout your body," that Amberen can support "the optimal function of your vital organs," that "Energy metabolism is soon restored," and that "Suddenly you feel younger!"

NAD also noted Lunada's decision to discontinue challenged testimonials, and to cease making its claim that the ingredients in Amberen are on FDA's Generally Recognized as Safe (GRAS) list. NAD determined that the discontinuation of these claims was necessary and appropriate.

NAD determined that the Maevsky study supported some of Lunada's performance claims. However, the study did not support the claim that Amberen can achieve "balanced production and circulation of hormones throughout your body." Nor did the study show that Amberen supports "the optimal function of your vital organs. Energy metabolism is soon restored. Suddenly you feel younger!" NAD therefore found that the advertiser's discontinuation of these claims was necessary and appropriate. NAD also recommended that Lunada discontinue its claims that Amberen relieves

“night sweats,” “moodiness,” and “inability to concentrate.”

Although the advertiser agreed to discontinue “complete” or “all in one” relief claims, NAD also cautioned the advertiser to cease suggesting or implying that Amberen provides complete—or even near-complete—relief of symptoms. While the Maevsky study showed that Amberen could “improve” or lessen various menopausal symptoms, these improvements were not shown to be dramatic or cure-like. NAD thus recommended that Lunada exercise caution and moderation in its advertising claims. NAD recommended that the advertiser discontinue its claim that Amberen will “last for up to 3 months.” NAD was satisfied that Lunada’s large body of evidence supports its claim that Amberen has been clinically tested and extensively studied for over 30 years.”

NAD was also satisfied with the evidence that was offered in support of the claim that its “proprietary technology produces perfectly shaped ‘smart’ molecules that your body can readily recognize and use. Inside your cells, these remarkable compounds rejuvenate mitochondria and rebalance hormone levels.” However, NAD found that the Maevsky study results did not support the claim that the product’s rejuvenating effects are “profound.” NAD therefore recommended that the advertiser discontinue claiming that the effects of Amberen are “profound.” NAD also determined that the advertiser had supported its claim to be “the only company in the world that has the technology to produce ‘smart molecules’ of succinates and fumarates (key ingredients in Amberen) with specific shapes that are bioidentical to the human body. Which means our compounds are shaped for optimal performance.”

The advertiser stated that it would consider NAD’s recommendations in all current and future advertising for Amberen.

DreamBrands, Inc.

Add Lib

Case # 5451 (April/May 2012)

NAD determined that, based on the scientific evidence provided, a dietary supplement advertiser provided a reasonable basis to support claims that the ingredient American Ginseng had been shown to enhance and improve mood provided that its dosing recommendations are consistent with the research on American Ginseng. NAD concluded that the advertiser’s scientific evidence was insufficient to support 1) claims for improved, restored or boosted libido in females and 2) unqualified claims of restoring, sustaining or increasing energy. NAD recommended that these claims be discontinued. NAD determined that the advertiser provided a reasonable basis for certain qualified “energy” claims provided the concept of “mental energy” is clearly explained, and directly connected to the mood benefits indicated in the scientific testing.

The advertiser stated that it accepted NAD’s decision and agreed to modify future advertising for the product.

Good Health Naturally, LLC

Serranol Supplements

Case #5441 (April/May 2012)

With the exception of three claims, NAD recommended that a dietary supplement advertiser discontinue all challenged claims because it did not conduct any studies on its Serranol product and because it only provided animal studies, informal summaries, abstracts or bibliographic references in support of the majority of its ingredient claims. NAD determined that the very few in vitro and in vivo full-text studies submitted by the advertiser were insufficient to support the advertiser's strong health claims. NAD further determined that the advertiser did not produce any evidence to support its safety claims, although the advertiser was free to tout ECE as an edible brown algae. Finally, NAD determined that the advertiser had reasonable basis for a claim that the curcumin in Serranol "reduces inflammation in joints" and that ECE is an antioxidant. NAD decided to refer the matter to the Federal Trade Commission.

Irwin Naturals

Doctor Developed Clear Pure Complexion

Case #5435 (3.2012)

NAD determined that a dietary supplement advertiser provided a reasonable basis for clearly qualified claims indicating that its Clear Pure Complexion supplement contained certain ingredients shown to improve the health and appearance of acneprone skin. In particular, NAD recommended that the advertiser expressly qualify its claims to communicate to consumers that the ingredient zinc was effective in the manner described in the advertising; that vitamin A might be helpful in reducing acne in vitamin A deficient patients; and that vitamin B6 might be helpful in treating acne in vitamin B6 deficient patients.

With regard to the product's "pro-nutraceutical complex," NAD believed that the body of evidence upon which the advertiser relied, could, when considered collectively, provide a reasonable basis for the general claim that the pro-nutraceutical complex contained ingredients that had been used in traditional medicine to "target internal factors that influence problematic skin." Thus, NAD recommended that the advertiser expressly qualify its claims in a way that communicated to consumers that the ingredients in the Pro-Nutraceutical Complex had been shown in historical or traditional use to "target internal factors that influence problematic skin."

Lastly, NAD determined that the advertiser's evidence was insufficient to provide a reasonable basis for the claim that "the formula has been scientifically-developed to target the vital organs and systems of the body that directly affect skin health." Thus, NAD recommended that the advertiser discontinue use of the phrase "scientifically-developed."

The advertiser stated that it agreed to respond constructively and effectively to NAD's

recommendations.

Vitanergy, Inc.
Urinozinc® Supplements
Case #5433 (3.2012)

NAD determined that a dietary advertiser's evidence was not sufficiently reliable to support its establishment claim "shown in clinical studies to help reduce symptoms associated with an enlarged prostate and improve urinary flow rate." NAD therefore recommended that the advertiser discontinue this claim.

NAD also determined that the advertiser had produced a reasonable basis for its claim that it was the "only prostate formulation with a US Patent," as it clearly identified that the formulation patent made the Urinozinc supplement unique. NAD noted the advertiser's responsibility to monitor the marketplace for any new supplements that also obtained a formulation patent that would render Urinozinc's exclusivity claim inaccurate. However, NAD recommended that the advertiser discontinue its claim, "helping alleviate symptoms associated with an enlarged prostate."

Lastly, NAD determined that the advertiser had provided a reasonable basis for ingredient based claims that the product was "formulated to support normal prostate function" and "for a healthy prostate, visit your urologist once a year and take URINOZINC®," but NAD recommended that the advertiser make clear that these claims were based on certain ingredients in Urinozinc and not testing conducted on the Urinozinc product itself.

The advertiser agreed to comply with NAD's recommendations.

EYESCIENCE LABS, LLC
Computer Eye Strain Formula™
Case # 5424 (2.2012)

NAD determined that all product performance claims made by a dietary supplement advertiser should be discontinued and any future claims should be strictly limited to the potential of an ingredient (6 mg of astaxanthin) and not of the actual product to help reduce eye strain and fatigue.

The advertiser stated that it would modify its advertising consistent with NAD's recommendations.

Barlow Herbal Specialties, LLC
LDM-100 Supplement
Case # 5421 (1.2012)

NAD appreciated a dietary supplement advertiser's participation in the self-regulatory process and its assurance that it would permanently discontinue its

claims “LDM-100 – Broad spectrum plant antibiotic, Virastatic, Bacteriostatic, Fungicidal (influenza, colds, respiratory and urinary infections, staph and strep infections, skin infections, warts, etc.),” “Destined to become one of the most important antibiotic herbs known to man. – ET Krebs” and “LDM-00 is our most popular formula. Now available for the first time in 2 oz. bottles.” NAD deemed permanent discontinuance of the claims necessary and proper given the lack of any supporting evidence in the record.

Direct Digital, LLC
Instaflex® Dietary Supplement
Case #5419 (1. 2012)

NAD determined that a dietary supplement advertiser had provided a reasonable basis for advertising claims that its Instaflex product could “relieve and comfort your joints,” “...increase flexibility,” “lubricate for healthy fluid movement,” and “protect and enhance you mobility.” In coming to this conclusion, NAD relied exclusively on the 1,500 mg of glucosamine in the Instaflex supplements.

Direct Digital appreciated in the NAD process and its conclusion.

Proprietary Nutritionals, Inc.
Sytrinol®
Case #5396 (11.2011)

NAD concluded that a clinical study on the dietary supplement SYTRINOL® provided a reasonable basis for claims that SYTRINOL® lowered and improved cholesterol, including the claims “30% improvement in Cholesterol in just 30 Days,” “Clinically Studied,” “Lowers Total Cholesterol,” “Lowers LDL,” and “Lowers Triglycerides.”

NAD determined that the research on the ingredients provided a reasonable basis for the claims that SYTRINOL® provided “Antioxidant Benefits” and “Anti-Inflammatory Benefits.” NAD, however, recommended that the advertiser discontinue its claim that “SYTRINOL® is a powerful antioxidant.”

NAD further determined that the advertiser provided a reasonable basis for claims that SYTRINOL® was “safe,” but recommended that the advertiser discontinue claims that SYTRINOL® had been “proven to be safe.”

Lastly, NAD was concerned about certain comparisons to statin drug therapy in the SYTRINOL® advertising, and recommended that they be discontinued.

The advertiser agreed to comply with NAD's recommendations.

Proven Results Health**Diab-X®**

Case #5393 (11. 2011)

The National Advertising Division found to be necessary and proper a dietary supplement advertiser's discontinuance of claims and modifications to its advertising, including the elimination of all of its testimonials, elimination of all express and implied claims that Diab-X, or the ingredients in it, could help reverse/prevent/cure diabetes. NAD is troubled by any claims promising that a dietary supplement can prevent or "cure" a disease condition like diabetes, and there was no evidence to support any such claims, including the following: "Imagine Your Life 'Free' of Diabetic Risks," "FREE from Diabetes Concerns? Like Heart Attack, Blindness, Amputation, Death and on," "Diab-X is: A Safe (See Studies), Completely Natural, Herbal Supplement that Supports Healthy Blood Sugar and works to help you enjoy that Diabetic Diet, And lose any extra Diabetic Weight," "Say NO To Diabetes With a Safe, All-Natural Supplement," "After two decades of safety and efficacy research, the key ingredients in Diab-X® have been demonstrated, along with a healthy diet and moderate exercise to provide help needed to support your fight to defeat diabetes naturally," "Defeat Diabetes Naturally!," "Eliminate the diabetic sugar cravings and hungar [sic] typically associated with high blood sugar and prescription drugs," "If you're searching for a natural supplement to help you reverse your Type 2 Diabetes, ask yourself the following questions: Does the product conform to tested ingredient grade strength and purity standards? Diab-X does," "The results of these exhaustive and expensive tests prove Diab-X® can help Type 2 diabetics achieve considerable weight loss and blood sugar normalization results, within just 90 days or less," "90 Days To Prove to Yourself Diab-X® is Everything We Promise! Help control blood sugar levels fast! More than 100 clinical trials by leading Universities! Lose diabetic weight! 3 times faster than diet and exercise alone! Customer proven!"

NAD concluded, however, that there was some evidence providing a reasonable basis for limited claims that the ingredients in Diab-X, particularly Super CitriMax and ChromeMate, could "promote healthy blood sugar levels," and "help suppress appetite."

Addressing the remaining claims, NAD recommended that the advertiser discontinue the claims "This proprietary blend decreases fasting plasma insulin by 25%, trig-lyceride levels by 17%, and insulin resistance by 16%," "Diab-X® has also received USP and NF certification, verifying, that it contains the stated ingredient level and potency as claimed," "No Side-Effects" "Does it work? - Yes, of course it does! Shown to normalize blood sugar, no other product can provide you with over 100 clinical studies from major universities [sic].""Sugar Cravings Go Away!" "...reduce your Body Mass Index (BMI) 3 times faster than diet or exercise alone...," "Super CitriMax® reduces body weight 3-times greater than diet and exercise alone" "Protect from age related metabolic disorders," "Improve exercise performance levels," "Inhibit fat synthesis and increase fat burning," "Restore your healthy Body Mass Index (BMI)," "Reduce anxiety and physical stress," "Protect your balanced cholesterol levels," and "Support your healthy circulatory system."

NAD also recommended that the advertiser discontinue using the logos of government agencies in its advertising, including USP, NF, NIH and FDA, to avoid any implication that this product, or its ingredients are somehow certified, or authorized by any of these agencies.

The advertiser stated that it accepted NAD's entire decision and agreed to modify or discontinue the advertising in question.

Dr. Enrico's Nutritionals, Inc.

Neuropasil

Case #5382 (11.2011)

NAD found that Dr. Enrico's provided a reasonable basis for general claims that Alpha Lipoic Acid can help alleviate symptoms associated with neuropathy, including stabbing pain, burning pain, paresthesia, and asleep numbness of the feet, when taken for five weeks at doses of 600 mg per day, less than the amount currently contained in the advertiser's Neuropasil product. Accordingly, to support any claims based on Alpha Lipoic Acid supplementation, NAD recommended that the advertiser modify the dosage/content of its product so that it provides a minimum dosage of 600 mg per day of Alpha Lipoic Acid.

NAD determined that the claims "Get quick relief from Nerve Pain with all-natural Neuropasil*" and "Neuropasil will help relieve your nerve pain so you can enjoy an active lifestyle,*" reasonably conveyed a message that the Neuropasil product itself had been studied and shown to be effective. NAD recommended that in future advertising, the advertiser make clear that the claims are based on ingredient research, not on any product testing.

NAD found that the evidence provided a reasonable basis for clearly qualified ingredient claims for Alpha Lipoic Acid: "Nerve Pain Formula," "Effectively Promotes Nerve Health," "Help relieve your pain...," "Neuropasil will help relieve your nerve pain so you can enjoy an active lifestyle.*," and "Its ingredients help decrease inflammation and increase healthy circulation naturally, to maintain optimum mobility and experience less pain."

NAD found that the claims of quick relief, e.g., "Get quick relief from Nerve Pain with all-natural Neuropasil*" were unsupported and recommended that they be discontinued.

NAD determined that the research provided a reasonable basis for the claim listing the various symptoms associated with neuropathy that stated, "Have You Experienced These Sensations? Numbness Tingling Pinching Burning Stabbing or sticking pain Electric shock Glove stocking sensation (when hands or feet are bare) Weakness Heaviness Cramps Symptoms can often become more pronounced at night—making sleep difficult."

NAD further determined that there was insufficient evidence to support the safety claims that Neuropasil has “absolutely no negative side effects—and does not interact with medications” and recommended that it, and other safety claims be discontinued. NAD found that the claim, “Neuropasil relieves the pain and symptoms associated with Nerve Pain, Peripheral Neuropathy, Diabetic Neuropathy, Carpal Tunnel Syndrome, Fibromyalgia, back and neck pain and numbness, tingling and burning in the hands and feet,” overstated the potential benefits of these ingredients, and recommended that the advertiser discontinue this claim, with regard to the other stated conditions, i.e., “Carpal Tunnel Syndrome, Fibromyalgia, back and neck pain.” NAD also found that the claim “Stop Suffering from Nerve Pain” also overstated the potential benefits of these ingredients, as there was no evidence that the participants in the ingredient studies experienced complete relief, and therefore, recommended that the claim be discontinued.

Lastly, NAD recommended that the advertiser discontinue the claims “America's Leading Remedy for Nerve Relief,” “Physician Endorsed,” and “all-natural doctor recommended Neuropasil,” as there was insufficient evidence to support these claims.

The advertiser stated that it would modify its future advertising taking into account NAD's concerns and recommendations.

NNC, LLC
Vitali-T-Aid™

Case #5373 (Sept./Oct. 2011)

NAD found that the results of a human clinical study on Testofen, the key ingredient in the dietary supplement Vitali-T-Aid, provided a reasonable basis for general, qualified advertising claims that Vitali-T-Aid, with resistance training, could help increase free testosterone levels, but because of the large observed placebo effect, the study could not support the advertiser's quantified claims that testosterone was boosted “by an average of 96% in just six weeks,” and NAD recommended that it be discontinued. NAD further found that the body composition results of this study could not support claims that Vitali-T-Aid “enhances muscle mass,” and recommended that it too, be discontinued.

NAD found that the results of the second study on Testofen, which recorded the participants' self-reported evaluation of their sexual function, performance, and satisfaction, provided a reasonable basis for general claims of “increased libido,” increased sexual cognition, increased sexual arousal, increased sexual behavior and improved orgasm, but was insufficient to support claims of self-reported “enhanced muscle mass and energy.”

NAD also concluded that the results of a “10 point” rating scale utilized in this study could not support the quantified claim that “85% of the clinical trial group reported an improvement in sexual desire and performance.”

NAD also recommended that the advertiser discontinue the claim "Supports Healthy Erectile Functions."

Further, NAD recommended that the advertiser discontinue the claim that Vitali-T-Aid "helps make men strong, sexy and virile again," as NAD found that it overstated the evidence.

Lastly, NAD recommended that when referencing the term "male menopause," such as "Scientific researchers have finally discovered a new natural compound that attacks the nasty symptoms of male menopause," the advertiser clearly delineate the symptoms to which it is referring.

The advertiser stated that it would make adjustments to its advertising consistent with the NAD's recommendations.

Nu Century Herbs

Resprin

Case #5356 (Sept./Oct. 2011)

NAD concluded that a dietary supplement advertiser's pilot clinical study and in vitro testing were insufficient to support performance claims for the supplement Resprin or its ingredients. NAD found that the advertiser could support certain general claims for the ingredients in Resprin based on traditional Chinese medicine evidence, including claims that Resprin can "support upper respiratory health," and was "...specially formulated with a unique blend of 23 herbs, to support respiratory health," but in doing so, the advertiser would have to make it clear that the claims were based on traditional Chinese medicine.

NAD also recommended, however, that the advertiser discontinue certain claims that it found to go beyond TCM-based evidence, including claims that Resprin could "naturally enhance your breathing," was "The natural way to clearer breathing," or would help you "Breathe easier."

The advertiser stated that it accepted NAD's conclusions and the recommendations and would take the recommendations into account in the language of its future advertising.

Cambridge Institute For Better Vision

Eyemax-Plus

Case #5349 (8.2011)

NAD determined that the significant modifications and discontinuances of eye disease prevention and treatment claims that a dietary supplement advertiser made to its website were necessary and proper.

NAD further recommended that the advertiser discontinue (1) the use of the term “protect,” (2) the use of term “stabilize,” and (3) references to “research” and “doctors,” as these claims were not supported by competent and reliable evidence.

The advertiser stated that it had removed the word “protect” from its website in accordance with NAD's recommendation.

Nordic Naturals, Inc.
Ultimate Omega Sport 90
Case #5344 (8.2011)

NAD concluded that test results done on raw fish oil could not support advertising claims for finished fish oil supplement products, particularly those that were formulations, combined with other ingredients, such as flavorings. As a result, NAD recommended that the advertiser of Nordic Naturals supplements discontinue the following advertising claims because they were based on testing conducted on the raw fish oil and not the finished product on the shelves:

- “Nordic Naturals’ patented, oxygen-free manufacturing process delivers peroxide values (indicators of freshness) down to absolute 0.0mEq/kg, with an average of 0.75 mEq/kg or approximately 14 times below the Norwegian Medicinal Standard and European Pharmacopoeia Standard limits”;
- “Nordic Naturals adheres to and exceeds the stringent Norwegian Medicinal Standard (NMS) and the European Pharmacopoeia Standard (EPS) as well as the voluntary standards set by the Council for Responsible Nutrition (CRN) and the Global Organization for EPA and DHA Omega-3 (GOED) for all of our products”; and
- “Our products consistently test far below acceptable national and international pharmaceutical limits.”

Similarly, NAD recommended that the advertiser discontinue a comparative claim stating that “Nordic Naturals has perfected fish oils by offering great taste, purity, and unmatched freshness levels” in the absence of any comparative testing in support.

While NAD found that the advertiser could tout the benefits of its refining techniques, NAD recommended that the advertiser discontinue its claim that “Our leading edge refining techniques reduces any potential toxins to undetectable amounts.”

Lastly, since the advertiser permanently discontinued the claim that, “The Norwegian Medicinal Standard for PCB's and HCB's is 3.0 ppt, while Nordic Naturals is testing down to 0.4 ppt without detection,” prior to the challenge date, NAD administratively closed the inquiry as to this claim.

The advertiser agreed to comply with NAD's decision.

Pharmavite LLC
Triple Flex Liquid Softgels
Case #5343 (7.2011)

NAD found that a dietary supplement advertiser provided a reasonable basis for claims that the willow bark extract in TripleFlex LSG helped to relieve the pain associated with osteoarthritis as measured at 7 days. NAD found to be necessary and proper the qualification that TripleFlex LSG begins to work in as little as 7 days.

NAD, however, found that the advertiser's claims as written could be understood by some consumers as referring to more than pain relief, and conveyed an un-supported message that joint health, mobility and flexibility were also improved "in as little as 7 days." Therefore, NAD recommended that the advertiser limit any "7 day" claims, which were based on the willow bark extract in TripleFlex, to claims that users will begin to feel pain relief and relief of joint comfort, and avoid any suggestion that joint health, or mobility and flexibility had been shown to improve in 7 days.

Lastly, NAD recommended that the advertiser modify its packaging to clearly qualify its claim of Triple Strength, and make it clear that Triple Strength only relates to the number of softgels that comprise a recommended daily serving.

The advertiser stated that it would take the NAD's findings into account in future advertising.

Rexall Sundown, Inc.
Osteo Bi-Flex
Case #5334 (7.2011)

The National Advertising Division determined that clinical research on the key ingredient in the dietary supplement Osteo Bi-Flex, Aflapin, provided a reasonable basis for the claims, "Joint support formula designed to show improvement in joint comfort within 7 days!" and "Features 5-LOXIN Advanced™—a patent pending special natural extract of Boswellia Serrata that shows improvement in joint comfort within 7 days."

NAD further found that the body of evidence on Vitamin D provided a reasonable basis for claims that it "Promotes neuromuscular function" and "Supports overall immune system health."

Lastly, NAD found that the current National Disease and Therapeutic Index ("NDTI") provided a reasonable basis for the claim that Osteo Bi-Flex is the "#1 Doctor & Pharmacist Recommended Brand."

New Nordic US INC.
Mulberry Zuccarin Dietary Supplement
Case #5333 (7.2011)

Because of the nature of the dietary supplement product Mulberry Zuccarin and the types of potential consumers that would purchase it (i.e., diabetics or those with blood sugar issues and potentially undiagnosed diabetes), NAD recommended that the advertiser include a prominent disclosure in all advertising advising consumers that “Mulberry Zuccarin is not a prescription drug,” and is “not intended to replace medications.”

The advertiser agreed to discontinue the claim, “1500 customers lost weight”, an action NAD deemed both necessary and appropriate.

NAD determined that the evidence in the record was insufficient to support weight loss claims, including a consumer testimonial by “Heidi” as well as claims that the product blocked carbohydrate digestion or stabilized blood sugar levels. Consequently, NAD recommended that these claims be discontinued.

NAD further determined that the advertiser’s evidence was not sufficient to support the rather strong product performance claims that Mulberry Zuccarin “blocks carbohydrate digestion” or “stabilizes blood sugar levels” and, consequently, recommended that both claims be discontinued.

Finally, NAD determined that the advertiser had sufficient evidence to support a claim that “Mulberry Zuccarin is a natural product, which helps maintain healthy blood sugar levels already within normal levels,” when 12 mg of the ingredient DNJ (1-deoxynojirimycin) are taken before each meal. Therefore, NAD recommended that the advertiser either change its product use instructions, and recommend 3 tablets (12 mg DNJ) before each meal, to match the amount used in a study, or discontinue the claim.

The advertiser stated that it would discontinue the advertising in question and include following disclaimer in future advertising: “Mulberry Zuccarin is not a prescription drug and is not intended to replace medications.”

Abbott Laboratories
Ensure Muscle Health
Case #5325 (6.2011)

NAD found that the body of research on HMB (a metabolite of the amino acid leucine), including research conducted on the target audience of the dietary supplement Ensure Muscle Health, elderly adults, provided a reasonable basis for advertising claims that “New Ensure® Muscle Health has Revigor, the amino acid metabolite HMB, and protein to help rebuild muscle and strength naturally lost over time,” and “Rebuild muscle, regain strength with New Ensure Muscle Health.”

Further, NAD found that the clinical research, coupled with the in vitro research on HMB also provided a reasonable basis for the advertiser's mechanism of action claims, discussing how Ensure Muscle Health works to provide the claimed benefits, including claims that, "New Ensure® Muscle Health has Revigor and protein to help protect, preserve and promote muscle health," "Protects muscles by strengthening the muscle cell wall," "Preserves muscle tissue by slowing the break-down of protein," and "Promotes muscle growth by in-creasing protein synthesis to help your body produce more muscle."

DSE Healthcare Solutions, LLC

Cystex

Case #5317 (April/May 2011)

NAD found that, because an advertiser was marketing two separate Cystex products, an OTC drug product and a dietary supplement product, each supported by a different body of scientific evidence, all advertising for these products had to be modified to make it clear which claims were associated with which product. NAD, therefore, recommended that the advertiser discontinue its claim that the Cystex® dietary supplement "Helps Manage UTIs" (urinary tract infections).

As to the performance claims at issue, NAD found that the evidence on the ingredients methenamine, sodium salicylate, and cranberry provided a reasonable basis for claims that "Cystex® is the trusted urinary health brand that has helped millions of women manage the pain and discomfort of urinary tract infections"; "If you are experiencing signs of a UTI, you can manage it with Cystex Urinary Pain Relief Tablets, the only over-the-counter urinary pain reliever available with a dual-action formula that not only eases the pain and burning caused by a urinary tract infection, but also contains an antibacterial (methenamine) to help the infection from getting worse while you wait for your doctor's appointment"; and "Cystex both manages the pain associated with a UTI and reduced [sic] the progression of the bacteria."

NAD also found that because of the acknowledged limitations to the cited study, the advertiser had to discontinue any claims solely based on that study.

The advertiser stated that it would take into account NAD's comments and recommendations in future advertising.

Peak Life, LLC

Somnapure

Case #5292 (3.2011)

NAD determined that a dietary supplement advertiser provided a reasonable basis for claims touting the sleep benefits of several of the ingredients in the product Somnapure, including melatonin, valerian, and hops, as well as the calming effects of several of the ingredients, including chamomile, lemon balm, and passionflower. Overall, NAD found that the advertiser was clear to tout the benefits of these ingredients in Somnapure, e.g., "Somnapure's superior formula contains herbal

ingredients such as Chamomile and Passionflower, which have a calming effect on the body..."

NAD did, however, find that certain elements of the Somnapure advertising conveyed the unsupported message that the product worked like a sleeping pill, i.e., take it once before you go to sleep and recommended that the advertiser modify the advertising to clarify the supported message, that in order to achieve the benefits of this product, one must take it regularly, over time.

Lastly, NAD recommended that the advertiser modify its website www.healthheadlines.com, to make it clear that it was advertising content created and controlled by the advertiser itself.

The advertiser stated that it would make appropriate adjustments to the format and presentation of certain claims consistent with the NAD's recommendations.

Pharmavite LLC
Nature Made GreatMind
Case #5284 (2.2011)

NAD found that the research on the nutraceutical formulation of GreatMind provided a reasonable basis for the claims, "Keep your mind great with Nature Made GreatMind!" "Enhances mental clarity and performance," "Naturally helps improve and maintain short- term memory," "Helps guard against normal cognitive decline associated with aging," "Nature Made GreatMind is an easy, natural and effective way to take care of your mind so you can stay clear, sharp and active," "Nature Made GreatMind has a unique, patent- pending formula that enhances mental performance, clarity and short-term memory with daily use," and "Nature Made GreatMind is formulated with key ingredients that your mind needs to stay healthy."

SkyMall, Inc.
Reversital
Case #5273 (1.2011)

NAD found that a dietary supplement advertiser's discontinuance of its unsupported health and disease prevention claims that "...Reversital® Reduces the risk of heart disease, liver disease, Alzheimer's, cancer, depression and type II diabetes, Fights infections and boosts the immune system, Reduces the risk of a stroke" to be necessary and proper.

NAD determined that the advertiser's discontinuance of its unsupported comparative performance claims versus other resveratrol supplements to be necessary and proper, including the claims that, "Reversital® (patent pending), a superior quality, highly purified supplement, reverses oxidative damage to cells and provides greater efficacy and performance than resveratrol alone," "It is the only natural supplement that contains the necessary combined molecules to activate the SIRT-1 enzyme and increase the body's defense mechanism by 35% more than resveratrol alone," and

“Reversitall to your daily vitamin regimen for a longer, healthier life. There is no comparison to any resveratrol product on the market.”

NAD further determined that the advertiser’s discontinuance of its claims that Reversitall “Improves physical and mental performance” and “Keeps skin healthy and supple” to be necessary and proper, as there was no evidence that Reversitall, or the ingredients in it, have been shown to yield either of the claimed benefits.

In the absence of any evidence that Reversitall was “Certified organic,” NAD found the advertiser’s discontinuance of this claim to be necessary and proper.

Lastly, NAD concluded that the existing evidence on resveratrol provided a reasonable basis for ingredient claims about resveratrol—“Revolutionary New Discovery Stimulates Longevity Gene!” and “And the truth is that red wine contains resveratrol, an extraordinarily powerful antioxidant with the ability to prolong cell life and to inhibit and delay the aging process.”

The advertiser agreed to comply with NAD’s recommendations.

Supple Beverages, LLC
Supple

Case # 5268 (12.30.10)

Supple Beverages represented that it had permanently discontinued many of the challenged claims, an action that NAD found to be necessary and proper. Specifically, NAD found that the advertiser’s discontinuance of its weight loss claims to be necessary and proper as there was no evidence to support claims that Supple will help “... you lose weight.” Further, NAD recommended that the advertiser discontinue claims suggesting that Supple works “fast” or “quick” as there was no evidence to support these types of “fast” onset of action claims.

As to the ingredients claims, NAD recommended that the advertiser discontinue its inaccurate claims disparaging glucosamine and chondroitin products generally, and limit any such future claims to the discussion of its own ingredients. In addition, NAD recommended that the advertiser modify the claim that “The active agents in Supple are prescribed by medical doctors as a first-line standard of care for joint suffering relief all around the world,” to clarify that the “active agents” referred to are glucosamine and chondroitin, and further, that the medical doctors prescribing them are in “other countries.”

NAD further recommended that advertiser must be careful to avoid conveying a message that the ingredients in Supple are U.S. FDA approved prescription or prescription strength.

NAD also found that the comparative claim that “Supple uses the highest strength of glucosamine and chondroitin that is highly regulated and sold as natural joint

rebuilding agents in over 40 countries," was unsupported, and recommended that it be discontinued.

Lastly, NAD found the advertiser's discontinuance of all of its current testimonials to be necessary and proper.

The advertiser stated that it would take NAD's comments and concerns into consideration in its future advertising.

DSM Nutritional Products, Inc.

i-flex

Case # 5267 (12.22.10)

NAD determined that the research on rose hip powder, the ingredient in the dietary supplement i-flex, was sufficiently reliable to support general claims that i-flex provided a joint health benefit. NAD found, however, that certain of the advertising claims, including quantified result claims, overstated the results of the research and recommended that the advertiser discontinue claims that "i-flex® from Patented Danish Rosehips Gives Rapid Joint Relief and Comfort to 4 out of Every 5 People" and "And the longer term effect is also impressive."

NAD also determined that in the absence of comparative research comparing the relative efficacy of glucosamine and rose hip powder, the advertiser could not support the comparative performance claims at issue. Therefore, NAD recommended that the advertiser discontinue its claims that "iflex works faster than glucosamine," and "i-flex patent-processed RHP works better than glucosamine." In addition, NAD recommended that the advertiser discontinue claiming that research had found no joint health benefit from glucosamine supplementation.

NAD further determined found the claims that i-flex was "All Natural" and "free of all super 8 allergens" were supported, but recommended that the advertiser discontinue its unsupported claims that i-flex was a "Green and sustainable ingredient."

NAD found that the claim that "i-flex is truly unlike any other joint product out there" was simply touting the fact that i-flex was the only rose hips joint health supplement of its kind, and therefore, found the claim supported. Similarly, NAD found that the claim, "Leap to a Higher Level of All Natural & Clinically Effective Joint Relief" in a monadic context, i.e., in the absence of the comparative claims versus glucosamine, was puffery, touting the benefits of the product in a fanciful manner.

NAD further recommended that the advertiser discontinue the claim "The formula has been used by thousands all over Europe with fantastic results in soothing sore joints" as it was not based on research.

Lastly, NAD recommended that the advertiser modify its newspaper advertorial to make it clearer that it was, in fact, advertising, and not news content.

The advertiser agreed to comply with NAD's decision.

Marabou Limited

GenFX

Case # 5266 (12.21.10)

NAD determined that Marabou provided evidence that oral supplementation with certain amino acids, in certain quantities, may increase the body's production of Human Growth Hormone (HGH), any claims regarding this benefit should be limited to indicate that they are based on emerging evidence.

NAD found that the claim that "Clinical tests prove it!" was unsupported and recommended that it be discontinued.

NAD also determined that the advertiser should be careful to avoid claiming, expressly or impliedly, that GenFX supplementation would yield benefits associated with naturally occurring HGH or FDA-approved HGH injections.

Accordingly, NAD recommended that the advertiser discontinue the claims, "We think that this is the biggest breakthrough EVER in anti-aging—does MORE than tens of thousands of \$\$ in plastic surgery, every known spa treatment and personal trainers combined," "GenFX™ has been formulated to help replenish your body's lost levels of Youthfulness, Vitality And Attractiveness!" "HGH injections cost up to \$15,000 and are available only to the super-rich! But now you can achieve the same results, simply and affordably," "Our HGH Releaser Formula is developed to replace injections of donor HGH and stimulate your own body to actually produce more of its own. GenFX is a simple once-daily solu-caplet that aims to restore your youthful levels of HGH," "Our HGH Releaser Formula is developed to replace injections of donor HGH and stimulate your own body to actually produce more of its own. GenFX is a simple once-daily solu-caplet that aims to restore your youthful levels of HGH," "No injections; No doctor's office visits; no painful blood monitoring; No unpleasant side effects!" and "Best of all, it's affordable—barely a tiny fraction of the cost of injectable HGH."

In addition, NAD recommended that the advertiser discontinue listing the benefits of HGH, including claims stating, "Decrease fat, while increasing lean muscle; Improve the look and feel of your skin; Prevent age spots; Increase bone density, and even reverse osteoporosis; Power up your brain, and maintain memory even as you age; Boost your sex drive; Maintain good vision and hearing; Tonify and improve overall physical and mental well being; Sleep better; Improve your mood, and banish depression and fatigue," and "With GenFX everything just works better—like a young person's body. If you have increased levels of HGH: you become better at fighting diseases, like stomach and lung conditions or even high cholesterol and high blood sugar, your sex life and sexual response are reinvigorated, You shed extra body fat in the belly, butt and legs, Your skin tone, texture and elasticity improve."

NAD also recommended that the advertiser discontinue its testimonials, including those stating, "The energy and fitness levels I had as a teenager have been restored to a

level I am very happy with. As an added bonus, my hair stopped graying and thinning. I have been on this product only 2 months!" "Becoming an old man is not much fun, but I refused to go down without a fight. GenFX™ has turned back the hands of time. I am no longer weak and incapable, and would recommend this to any people who want to extend the best part of their lives," "I was diagnosed with clinical depression 10 years ago. It was so bad that I barely left my house. The stress aged my face and body and I looked much older than I actually was. My doctor introduced me to GenFX™ HGH Releaser, and within just a few months, my frown lines are beginning to disappear. I am also more energetic and do feel like I've gone back in time," and "I had a hard time falling asleep at night since the age of 23. After using GenFX™, I now consistently get a full 8 hours. This product has changed my entire life!"

NAD further recommended that the advertiser discontinue the claim that "GenFX™ has no reported side effects," and "Clinical tests prove it! GenFX™ has no reported side effects."

Lastly, NAD found that the claims that "We think that this is the biggest breakthrough EVER in anti-aging—does MORE than tens of thousands of \$\$ in plastic surgery, every known spa treatment and personal trainers combined," "GenFX has been formulated to replenish your body's lost levels of Youthfulness, Vitality, and Attractiveness!" and "GenFX™ may be the very best overall anti-aging and revitalizing tonic ever!" are both unsupported overstatements of the benefits of GenFX and recommended that they be discontinued.

The advertiser agreed to comply with NAD's recommendations.

Pacific Shore Holding, Inc.

Burner Balm®

Case # 5250 (11.18.10)

NAD determined that the advertiser's voluntary discontinuance of the following claims was necessary and proper given the absence of competent and reliable supporting evidence:

- "Burner Balm's effectiveness is twofold. First, the ingredients are absorbed into the blood stream through the many blood vessels located in the mucus membrane in a person's lips. Secondly, as with any lip balm or lipstick, a person will continually lick their lips and swallow while the product is on their lips. Thus, the Burner Balm ingredients are absorbed faster, steadier and more efficiently into the bloodstream than ingesting pills, powder supplements or drinks";
- "Our revolutionary DOCTOR Formulated Burner Balm lip balm is made with Green Tea, Hoodia Gordonii Extracts, Chromium Picolinate and Caffeine. These ingredients have all been proven for many years to be very effective in dietary supplements";
- "I Lost 8 pounds in 4 weeks with Burner Balm"; and

- “The use of a dietary lip balm is far less invasive than ingesting pills and drinking diet potions, which can commonly cause other side effects and complications in patients like upset stomachs and anxiety.”

Urban Nutrition, LLC

RestAid®

Case # 5224 (9.24.10)

NAD determined that Urban Nutrition demonstrated that the melatonin in its RestAid product had been shown to provide a sleep benefit and help promote sleep, but that the evidence was inconclusive as to the sleep benefits of the other ingredients and the product itself. NAD recommended that the claim RestAid has been clinically proven to help one to “fall asleep faster, sleep deeper and awake more refreshed” be discontinued.

Similarly, NAD recommended that the advertiser discontinue referring to RestAid as “the non-prescription sleeping pill,” and the claim that “RestAid is the non-prescription sleeping pill that is clinically proven to help you fall asleep faster, sleep deeper, stay asleep throughout the night, and wake up feeling great.” NAD recommended that, in future advertising, the advertiser limit any claims touting direct sleep promoting benefits to the melatonin in RestAid and, in discussing the ingredients, modify its advertising to accurately reflect the evidence on each of those ingredients.

NAD also found no evidence to support the claim that “Its delivery system gets the nutrients into the blood stream much quicker than other supplements” and, therefore, recommended that this claim be discontinued. NAD found that the advertiser's discontinuance of the claim “94% of users fall asleep during that initial 15-30 minutes,” was necessary and proper as there was no evidence to support this claim. Lastly, NAD found that the advertiser's discontinuance of all testimonials comparing RestAid with Ambien, Lunesta, and other prescription and over-the-counter sleep-aid products, was necessary and proper. NAD recommended that in future testimonials, the advertiser avoid overstating the benefits of the ingredients in RestAid.

The advertiser stated that it would modify its advertising in accordance with the NAD's decision.

Celsius, Inc.

Celsius®

Case # 5217 (9.17.10)

NAD determined that Celsius provided a reasonable basis for the claims “increased metabolism” “calorie burning,” “fat loss,” “decrease in body fat,” “greater endurance performance,” “greater resistance to fatigue (increased energy),” and “Fat Loss,” as long as the claims were presented in the context of advertising geared towards people who exercise and made it clear that the promised benefits were based on drinking the advertiser's Celsius supplement and exercising.

NAD further recommended that the advertiser modify the claim that "Multiple studies have shown a single serving of Celsius on average burns up to 100 calories or more by raising metabolism over a three hour period, generating increased energy and alertness," to a more general claim that Celsius combined with exercise, can burn calories. In addition, NAD found that the claims "Celsius burns calories without sacrificing taste. Celsius is designed to be a healthier alternative" and "Good for you ingredients, such as Green Tea with EGCG, Ginger, Calcium, Chromium, B vitamins, and vitamin C, all which work together to raise metabolism, resulting in a sustained calorie burn while keeping you energized" were both supported in the context of advertising making it clear that Celsius combined with exercise yielded the claimed results. NAD also found that the modifications the advertiser made to its packaging and advertising materials, removing the words "BURNS CALORIES" and "Burn up to 100 Calories and more in each can!" from the cans, and adding the tag line "Your Ultimate Fitness Partner" helped to convey the "exercise" message, and therefore, were necessary and proper.

Lastly, NAD recommended that the advertiser discontinue the specific percentage claims "78% greater fat loss," "114% greater decrease in body fat," "79% greater endurance performance," "32% greater resistance to fatigue (increased energy)," and "5.5 lbs of Fat Loss" because they were based solely on the results of one study and overstated the benefits achieved.

The advertiser stated that it would take NAD's recommendations into account in future advertising.

Bell Lifestyle Products, Inc.

Bell Shark Cartilage #1

Case #5207 (08.25.10)

The Council for Responsible Nutrition challenged claims made by Bell Lifestyle for its Bell Shark Cartilage #1 dietary supplement including, but not limited to, the following: "Bell Shark Cartilage #1. Works in virtually all cases for 1. Osteoarthritis (worn cartilage) 2. Rheumatoid arthritis (chronic progressive) 3. Sciatica (lower back pain, leg pain, heel pain) 4. Neck pain and back pain 5. For Carpal Tunnel Syndrome (wrist pain) more information see product #30" and testimonials such as "Cancelled knee replacement. I was in pain and limping. Have no more pain now. Can dance square dance for hours."

NAD concluded that the evidence in the record was insufficient to establish a reasonable basis for the challenged joint health claims and therefore, recommended that they be discontinued. NAD noted, however, that if the advertiser can establish through competent and reliable scientific testing, that Bell Shark Cartilage #1 delivers 1,500 mg of glucosamine in a daily dosage, it can rely on the existing body of research on glucosamine to support limited joint health benefit claims. NAD, however, found that in any event, many of the claims at issue could not be supported by the research on glucosamine and chondroitin, and, therefore, recommended that they be discontinued. In addition, NAD recommended that the advertiser discontinue the

unsupported claims touting the overall efficacy of the product, such as “The only natural medicine on the market with a Money-Back Guarantee: It works in 98% of all cases,” “A 10 year success story with tens of thousands of men and women that have less pain or no pain at all. No side effects,” “Millions of men and women with knee, hip, and hand arthritis could be helped quickly, inexpensively and with virtually no side effects with this natural product,...,” “98% of people who try Bell Shark Cartilage live without arthritis pain.”

NAD also recommended that the advertiser discontinue all testimonials making unsupported pain relief and disease cure claims, and also those making and those making comparisons to medical treatments.

Addressing some of these issues, NAD noted that the advertiser represented that it has discontinued (1) all claims and testimonials referencing treatment of a specific disease, including claims comparing the relative efficacy of Bell Shark Cartilage to synthetic drugs, (2) the performance claims referencing the absolute number of users helped by Bell Shark Cartilage, (3) the claims that reference a specific percentage efficacy, and (4) the testimonials referencing alleviation of serious rheumatoid arthritis symptoms and the statements of the consumers who wrote that they avoided surgery after using Bell Shark Cartilage, all actions that NAD found necessary and proper as there was no evidence to support these claims.

The advertiser agreed to comply with NAD's recommendations.

The Elations Company, LLC
Elations Liquid Supplements
Case #5196 (07.14.10)

NAD challenged claims by Elations for its liquid supplements including: “A clinical study shows that people with joint discomfort who drank Elations experienced significant improvements in joint comfort in six days, with very strong results in as little as 3 days!,” “is more absorbable than pills,” “improves joint comfort in six days—faster than any other leading joint supplement brand” and testimonials such as “... after drinking Elations for 3 days, I went to work and didn't have the discomfort...”

NAD concluded that the advertiser's evidence was insufficient to support the specific establishment claim that Elations provides “significant improvements in joint comfort in six days, with very strong results in as little as 3 days” as well as its claim that Elations improved joint comfort “faster than any other leading joint supplement brand” and recommended that these claims be discontinued. However, NAD determined that the body of evidence upon which the advertiser relied could provide a reasonable basis for properly qualified claims about product and its intended function, and the promising results regarding certain studies on the ingredients in Elations including, but not limited to, glucosamine and chondroitin. NAD also concluded that the evidence relied upon by the advertiser provided a reasonable basis for its faster absorbability claims but cautioned that any such claims be properly qualified so as to avoid the implication that faster absorbability translates to superior efficacy of its product.

With respect to the claim, “drink just one bottle [of Elations] every day for stated results”, NAD concluded that, to the extent that the “stated results” refer to performance benefits at six days (or as little as 3 days), NAD recommended that this claim be discontinued. However, nothing in decision precludes the advertiser from claiming “drink just one bottle every day” to receive the benefits of glucosamine and chondroitin (as previously discussed). NAD concluded that the body of evidence provided by the advertiser provided a reasonable basis for its claims that “[b]oron helps the body to retain calcium whether or not Vitamin D is present...” and similar claims. NAD also appreciated the advertiser’s voluntary agreement to modify its claim, “Boron: Helps Retain 40% More Calcium” to more accurately reflect the underlying evidence that “Boron Helps Retain 35.7% More Calcium.” NAD also determined that the evidence provided a reasonable basis for the advertiser’s claims that “the combination of these ingredients in CCM can more effectively strengthen bones compared to calcium alone because CCM has better absorbability, meaning your bones will ‘drink it up’ ... whether or not Vitamin D is present” and that “[c]linical studies report that Calcium absorption from CCM was 26% greater than that of calcium carbonate.”

NAD further concluded that the testimonials concerning more general “joint relief” testimonials were adequately supported. However, with respect to those testimonials stating that Elations is effective after 3 days, one week, or two weeks, NAD recommended that these testimonials be discontinued.

The advertiser agreed to comply with NAD’s recommendations.

MuscleMeds, Inc.

Methyl Arimatest

Case #5190 (06. 21.10)

NAD challenged claims by MuscleMeds for its Methyl Arimatest including the following: “Increases Testosterone to Over 10,000 pg/mL,” “Clinically Tested,” and “Breakthrough Dual Action ‘Testosterone Looping and Pooling’ Effects.”

NAD found that a clinical study provided a reasonable basis for claims that the Formula 1 in Methyl Arimatest is “Clinically Tested.” Further, NAD found that the advertiser can rely on that study to support claims of “increased testosterone” observed in the participants in that study. NAD, however, recommended that when expressing the results in any advertising, the advertiser provide a context, and express the study’s results in terms of how much (e.g., the percentage) of an increase in testosterone, instead of simply claiming the resulting amount.

NAD found that the claim, “Breakthrough Dual Action ‘Testosterone Looping and Pooling’ Effects” was an accurate description of the mechanism of action of Formula 1. However, NAD recommended that the advertiser discontinue the claims that “Methyl Arimatest represents the greatest breakthrough in testosterone supplementation history, featuring a level of hardcore potency and effectiveness that has never been experienced before. Even the most elite professional bodybuilders are

proclaiming the new Methyl Arimatest to be the most powerful anabolic agent they have ever taken" and "Put Methyl Arimatest to the test and watch your testosterone levels skyrocket through the roof..." because they overstate the results of the study.

Lastly, while NAD found that the product packaging makes it clear that the product is two separate components, NAD recommended that the advertiser make its print advertising clearer that the product is two separate, distinct formulas. Further, NAD found that any advertising should also make it clear that Formula 1 has been clinically tested and not imply that Formula 2, or the combination of the two formulas, has been clinically tested.

The advertiser agreed to comply with NAD's recommendations.

Millenium Health LLC
Ellagic Acid Professional Grade 1,000 mg
Case #5188 (06.14.10)

The Council for Responsible Nutrition (CRN) challenged claims made by Millenium Health such as "Ellagic Acid is a proven anti-carcinogen, anti-mutagen, and anticancer initiator," "Ellagic Acid may be one of the most potent ways to fight Cancer. Ellagic Acid, a phenolic compound, inhibits the growth of cancer cells and arrests the growth in persons with a genetic predisposition for the disease," and "Ellagic Acid Study – The Hollings Cancer Institute at the University of South Carolina has conducted a double blind study on a group of 500 cervical cancer patients that had everyone excited. Nine years of study have shown that a natural product called Ellagic acid is causing Garrest within 48 hours (inhibiting and stopping mitosis-cancer cell division), and apoptosis (normal cell death) within 72 hours, for breast, pancreas, esophageal, skin, colon and prostate cancer cells." CRN also cited to a 2009 warning letter from the FDA to the advertiser explaining that the citation of publications to promote a product is evidence of the product's intended use.

Millenium Health explained that it voluntarily discontinued the challenged claims. However, NAD remained concerned about other claims on the advertiser's website which posed similar concerns. NAD recommended that in future advertising for this product, the advertiser make it clear that it is an antioxidant, and that as an antioxidant, possesses certain potential benefits, without suggesting that it can prevent, treat or cure cancer.

The advertiser agreed to comply with NAD's recommendations.

Imagenetix, Inc.
InflameAway® Celadrin®
Case # 5167 (4.27.10)

NAD found insufficient evidence to support any advertising claims comparing a joint comfort dietary supplement (Celadrin) to glucosamine and, therefore, found the

advertiser's voluntary discontinuances of these comparative claims to be necessary and proper.

As to the remaining claims, NAD found the evidence to be too inconsistent to support an establishment claim, and recommended that the advertiser discontinue the claim that Celadrin had been "Clinically tested and shown to be effective for improving joint comfort," or modify it to a more limited, general claim that Celadrin could provide a joint health benefit. Lastly, NAD found that the claim that "Patented InflammAway® Celadrin® is a medical breakthrough," was not supported by the research on Celadrin or the patent on its key ingredient, and NAD recommended that the claim be discontinued.

The advertiser stated that it would discontinue the challenged claims.

Health King Enterprise & Balanceuticals Group, Inc.

JointFlexer

Case # 5162 (4.12.10)

NAD recommended that all future advertising for the dietary supplement JointFlexer be modified to make it clear that the claims were based on ingredient research and not on any testing on the product itself. NAD also found that while the inclusion of the ingredient glucosamine in a dosage proven efficacious could support certain limited ingredient joint health claims, there was no evidence that glucosamine supplementation at the lower dosage included in the product provided a benefit. NAD recommended that the advertiser either increase the dosage of glucosamine to the efficacious level or discontinue claims including the following: that JointFlexer "Delivers essential nutrients for joints and maintains normal metabolism of skeleton and joints," "Promotes absorption of calcium and effectively inhibits joint degeneration," "Lubricates joint, reduces friction and prevents injuries of the joints."

NAD further found that claims suggesting JointFlexer be used for those suffering from "rheumatic arthritis," "rheumatoid arthritis" and "osteoporosis" overstated the evidence, and recommended that they be discontinued. Similarly, NAD recommended that the advertiser discontinue listing "Children who have hypogenesis of bones" and "Patients in post-operative recovery after bone fracture." as "indications for the use of JointFlexer, as there was insufficient evidence that the product or its ingredients would result in a positive benefit for sufferers of those conditions.

NAD also found insufficient evidence to support the claim that JointFlexer "Reduces and relieves pain." NAD found to be necessary and proper the advertiser's discontinuance of a testimonial stating that "My sister had a very bad swollen knee, she couldn't feel her knee-cap and couldn't bend her knee properly to use the restroom. She was hospitalized for one month but that didn't help. After trying 3 bottles of JointFlexer the swelling was gone. For the first time in 6 years she can feel her kneecap and is able to use the restroom without pain. She is very happy and grateful she found Balanceuticals Group" based on insufficient evidence.

NAD further recommended that the advertiser modify that the claim “Used for centuries, proven by clinical trials & research in China” to make it clear that this applied to the Traditional Chinese Medicine (herbal) ingredients in JointFlexer, and not the product itself or the glucosamine or Vitamin C in the product. NAD found that the advertiser’s modification of the claim that JointFlexer is “made of herbal extracts free of pollutants” to state “made of herbal extract in order to remove impurities from the raw materials” made it clear that the impurities were being removed from the supplement, and not from the body of the person taking it.

The advertiser agreed to comply with NAD’s recommendations.

Pharmavite, LLC

Pharmavite LLC Nature Made® Prenatal + DHA Liquid Softgel Vitamins

Case # 5160 (4.8.10)

NAD recognized that Nature Made® Prenatal + DHA Liquid Softgel vitamins are, in fact, the first prenatal multivitamin to combine DHA and folic acid in a single daily dose. However, NAD determined that there was insufficient evidence to establish the bioavailability of the folic acid in the product. Because of the important health issues relating to the need for expectant mothers to take 800 mcg of folic acid a day to reduce the risk of neural tube defects in their infants, NAD recommended that the advertiser discontinue marketing this product as a “complete” prenatal vitamin, unless and until the advertiser conducts further, competent and reliable testing that establishes the bioavailability of the folic acid in this product. NAD’s recommendation applied to the following claims: “Nature Made® knows that pregnant and nursing moms have special health needs for the development of their child. That’s why Nature Made® offers the first OTC supplement that combines a prenatal multivitamin with DHA in one single softgel,” “Now, you can simply swallow one single softgel to receive the daily dosage of nutritional support recommended for pregnant and nursing moms,” “... formulated with 23 key vitamins, minerals, and essential Omega-3 Fatty Acids that may benefit the neurological development of the fetus and health of the mother during pregnancy and may reduce the risk of having a child with brain or spinal cord birth defects,” and “Formulated for Easy Absorption.”

The advertiser stated that it accepted NAD’s recommendations.

Syntratech Corporation

Syntra-5 Total Body Solution

Case # 5150 (3.17.10)

NAD found that a dietary supplement advertiser’s research supported general performance claims that its Syntra-5 supplement has been “Clinically Tested for Optimal Support of: 1. Weight Management, 2. Blood Sugar, 3. Cholesterol, 4. Blood Pressure, 5. Triglycerides” and that “Syntra-5 is a clinically tested, proprietary, eleven ingredient formula that has under-gone extensive research and is designed to support weight management, blood sugar, cholesterol, blood pressure, and triglycerides.”

NAD, however, found that the one small study was insufficient to support the quantified performance claims that Syntra-5 resulted in a reduction of "Fasting Blood Sugar - from *196 to 89, Hemoglobin A1c - from *7.7 to 4.66, Cholesterol - from *338 to 240, Triglycerides - from *225 to 203, Blood Pressure - *171/75 to 146/70." NAD, therefore, recommended that the claims and testimonials be discontinued.

NAD also recommended that the advertiser discontinue any and all comparisons to pharmaceutical and medical treatments for diabetes, including the claim that, "No other product, pharmaceutical or natural, has achieved more effective results in controlled clinical studies than Syntra-5. Real science, real people, real results." NAD also found the advertiser's discontinuance of its claim that Syntra-5 was the "#1 RECOMMENDED Blood Sugar Discovery!" to be necessary and proper, as the claim was based on insufficient evidence.

The advertiser stated that it would take all NAD recommendations into account in future marketing efforts.

Lifes2good Natural Healthcare

Viviscal

Case # 5136 (1.13.10)

NAD found that testing on the dietary supplement Viviscal supported the advertising claim that "Viviscal strengthens and nourishes thinning hair from within while promoting existing growth." NAD found that these same studies supported claims that Viviscal was "safe," and that its ingredients were "natural," but recommended that the advertiser modify the claim that "100% natural ingredients make Viviscal safe and free of harmful side effects" to avoid conveying the message that the reason Viviscal was safe was because the ingredients were natural. NAD recommended that the advertiser modify its advertising to avoid any implication that Viviscal had been proven to work in, or had been designed for, women. NAD also recommended that the advertiser discontinue its claims that "Viviscal was doctor recommended." Further, NAD recommended that the advertiser discontinue its "before and after" photo comparison. NAD found the advertiser supported its claims that Viviscal was "Recommended by top celebrities and models."

The advertiser stated that it would take NAD's recommendations into account in future advertising.

Cobalis Corporation

PreHistin

Case # 5135 (1.11.10)

NAD found that the claims that "PreHistin® is the World's First Pre Histamine" and "PreHistin® is a 'pre-histamine' which means it regulates the release of histamine" were reflections of the mechanism of action of the product. Accordingly, NAD found that the claims not only were supported, but were important explanatory language as to how the product worked, as distinguished from other allergy products on the market.

NAD also determined that the results of the advertiser's clinical studies supported the claims that "PreHistin® was clinically shown to effectively maintain healthy IgE levels which have been linked to allergy symptoms such as sneezing, nasal congestion, and runny nose" and "PreHistin has been shown to effectively regulate IgE levels in individuals while significantly increasing serum vitamin B12 levels." NAD noted that the claims avoided asserting that PreHistin would result in symptom relief. NAD also found that these studies supported the claim "Yes. PreHistin® has been clinically tested for several years by well known U.S. allergists."

As to the claim that "PreHistin helps build up your immune system and has been shown to keep working for weeks after you stop taking it," NAD was satisfied that the B12 supplementation, in fact, helped build the immune system, but found insufficient support for the claim that it worked for "weeks after you stop taking it," and, accordingly, recommended that the advertiser discontinue this part of the claim. Based on the fact that none of the study participants taking PreHistin reported any side effects, NAD found the claims that "PreHistin® is free from side effects such as drowsiness" and "Clinical studies using PreHistin® showed no side effects when compared to the placebo" were supported. Further, since PreHistin was essentially a Vitamin B12 supplement, NAD found that the claim "All Natural Formula" was supported.

As to the claim that PreHistin was "Allergist Recommended," although the advertiser presented a list of allergists that used and recommended PreHistin to patients, the list did not rise to the level of a survey of physicians that would be required to support a "doctor recommended" claim, and therefore, NAD recommended that the claim be discontinued. The advertiser stated that it would modify its advertising claims as recommended by NAD.

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- Electronic Retailing Self-Regulation Program
- National Advertising Division
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