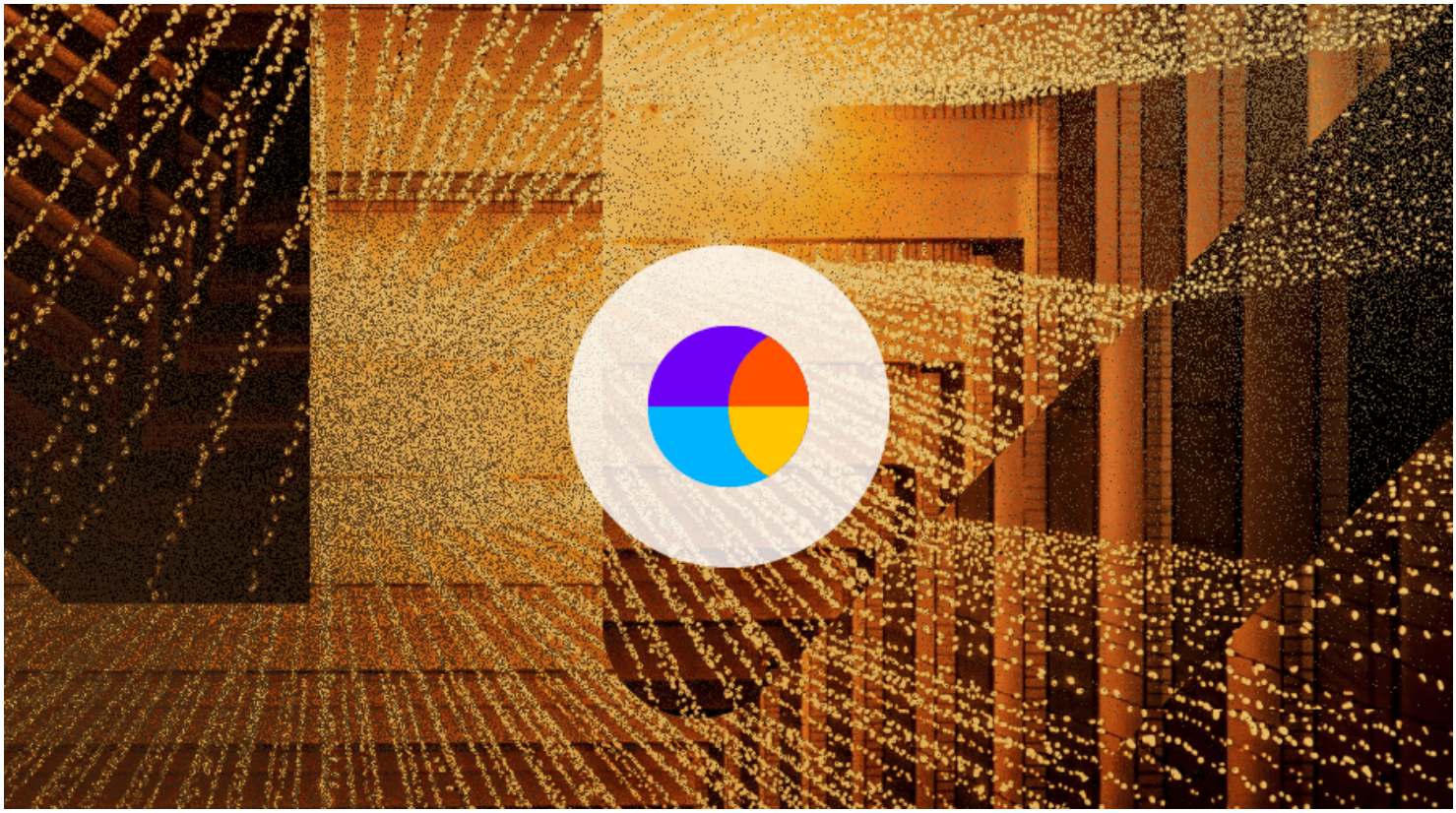
- Vendor Privacy Program
- Volkswagen Car-Net & Audi Connect

Our 501c3 Foundation



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BBB NATIONAL PROGRAMS

Direct Selling Self-Regulatory Council
Case #167-2024: Monitoring Inquiry – Zurvita Holdings, Inc.

Company Description

Zurvita Holdings, Inc. ("Zurvita" or the "Company") is a direct selling company that sells energy drinks and other nutritional health supplements. The Company is headquartered in Irving, Texas and was founded in 2008.

Basis of Inquiry

The Direct Selling Self-Regulatory Council ("DSSRC") is a national advertising self-regulation program administered by BBB National Programs. Pursuant to section V(A) of DSSRC's Policies & Procedures, any person or legal entity may provide DSSRC a written submission regarding any earning claims or product claims disseminated by or on behalf of a direct selling company, which such person or legal entity believes should be modified or discontinued.

In this instance, a non-governmental advocacy group ("NGO")[1] identified certain product performance claims disseminated by the Company that the NGO believes overstated the efficacy of Zurvita products.

The NGO also questioned the relevancy and reliability of a clinical study referenced on the Zurvita website which, according to the Company, supported several of the health-related claims at issue.

DSSRC identified the following representative claims in its Notice of Inquiry:

1. Zeal Wellness
    - "Made in USA"
    - "Clinically shown to reduce stress and increase productivity"
    - "Clinically Studied: In an independent clinical study* results showed that, by drinking two servings of Zeal a day, 85% of healthy participants experienced improved overall mood and a 23% increase in vigor and activity, as well as less anxiety and fatigue."
    - "The difference is backed by science. A study from independent third-party research firm KGK Synergize confirms that the positive benefits of drinking Zeal include improved mood, stronger vigor and vitality and less anxiety and fatigue."
    - "Zeal has been clinically shown to reduce stress and increase productivity while making you feel vibrant, focused, calm and confident. Zeal's natural source of clean energy can provide a boost of consistent and stable, long-lasting energy throughout your day."
2. Zurvita Burn
    - "Zurvita's dietary supplement designed specifically to optimize your metabolism, and improve your strength and performance. It supports healthy blood glucose levels and helps aid in overall health and wellness. Available in a 30-day supply of 60 capsules. Zurvita supplements are essential to supporting a healthy and active lifestyle. When taken together, they work to maintain healthy bodily function, allowing you to be your best, inside and out."
3. Zurvita Performance R3PAIR
    - "Zurvita Performance R3PAIR is a great-tasting, berry-flavored post-workout solution that accelerates muscle recovery through premium restorative ingredients, helps to reduce muscle soreness and inflammation, while also stimulating nutrient uptake. Available in 30 servings per canister or box of 10 on-the-go stick paks."
    - "Clinically- tested and athlete- recognized, our products are backed by award- winning ingredients, scientists, doctors and inspired by nature's best resources. And we believe in them so much, they come with a money-back guarantee."
    - Before and after weight loss depictions
4. H2O Hydrating Mix
    - "Scientifically backed"
5. Zundora
    - "Clinically proven to provide healthier-looking hair, skin and nails. Zundora can reduce the appearance of fine lines and wrinkles in just 28 days for your beauty on the outside."
6. Recovery Essentials System (Zundora/R3PAIR/H2O Hydrating Mix)
    - "This wonderful bundle is designed to accelerate muscle recovery, boost hydration levels, and support healthy skin, hair, nails, and joint mobility. It is the first step to preparing your body for peak performance by supporting your muscles and joints with nutrient-dense ingredients that are clinically clean and effective and keep you hydrated."

NGO Position

According to the NGO, when considering the study's limitations to support clinically proven claims for Zeal Wellness, citing scientific studies often requires conveying essential discussions about the preliminary nature of the results and the significance of factors such as longitudinal testing, scope, sample size, and testing methodology.

The NGO asserted that the term "significant" is frequently misunderstood and misused by advertisers and noted that statistical significance holds value in testing settings and applying the same language to suggest meaningful benefits to consumers can lead to misleading implications, especially without adequate explanation of the overall context and sample size changes.

The NGO maintained that the administrators of the study acknowledged certain limitations in drawing specific conclusions. Notably, it was stated that while the initial findings regarding the Zeal Wellness formulation's impact on mood states in moderately stressed populations are noteworthy, definitive conclusions require further directed research.

Additionally, the NGO expressed concerns regarding the applicability of the study's findings. Given that the majority of participants were not prior dietary supplement users, the NGO raised questions regarding the product's efficacy for those already taking supplements, a point highlighted by the study itself.

Furthermore, it was maintained that the study's limitations include a relatively small sample size and short trial length, raising questions about the robustness of the findings. The reliance on self-reported data, with the exception of the safety markers analysis, further complicates the interpretation of statistical benefits.

Moreover, the NGO stated that the study's authors' affiliation with Zurvita's scientific advisory board raised questions about potential biases, although the NGO conceded that this does not necessarily discredit the observed benefits.

Lastly, the study acknowledges the need for more precise measurement techniques to ensure methodological rigor and applicability to broader populations, suggesting that further refinement is necessary to draw more definitive conclusions.

Company Position

1. Zeal Wellness

As support for the establishment claims at issue, the Company submitted a randomized, double-blind, placebo-controlled, four-arm parallel study of 99 participants that evaluated the efficacy of its Zeal Wellness product on a variety of outcomes in healthy adults with moderate stress for a supplementation period of 28 days (the Evans study).[2] The objective of this study was to investigate the effect of Zeal Wellness on standardized measures of mood states, including overall feelings of vitality, in healthy, moderately-stressed adults.

Participants were randomized to one of four groups and received either Zeal Wellness once daily (1-dose-Zeal Wellness; 14g), Zeal Wellness twice daily (2-dose-Zeal Wellness; 28 g), placebo once daily (1-dose-placebo), or placebo twice daily (2-dose-placebo) for four weeks.[3] A stress/vitality questionnaire assessed stress and the Profile of Moods (POMS) Questionnaire assessed vigor via mental/physical energy and global mood state.

The results of the study indicated that participants receiving 2-dose-Zeal Wellness reported a 6.6% decrease in scores on POMS-Total Mood Disturbance (TMD; $p < 0.05$) and a 6.8% decrease in the anger-hostility mood state ($p < 0.022$) compared to the combined placebo group at day 29. The 2-dose-Zeal Wellness provided a 12.8% greater improvement in POMS-TMD scores when compared to participants receiving 1-dose-Zeal Wellness after 28 days of supplementation ($p = 0.014$). Within groups, there was a 22.4% and a 9.6% decrease in POMS-TMD scores in participants with 2-dose-Zeal Wellness and 1-dose-Zeal Wellness, respectively. In addition, participants receiving 2-dose-Zeal Wellness showed significant improvements ($p = 0.001$) in the POMS t-score iceberg profile[4], which represented a shift to a more healthy profile.

According to the Company, the testing data demonstrated that daily supplementation with 2-dose-Zeal Wellness significantly decreased POMS-TMD scores and anger-hostility mood states and shifted the POMS Iceberg profile to a healthy profile compared to the combined placebo, reflecting the functional benefit of a rice-bran-fruit-vegetable extracts-based beverage on health. Zurvita also engaged an expert scientist who provides regulatory oversight and manages the clinical trial application process for Health Canada to provide DSSRC with his evaluation of the reliability of the study results.[5]

- *"Made in the USA"*

During the pendency of the inquiry, Zurvita indicated to DSSRC that the "Made In USA" claim was dropped based upon global sourcing of raw material inputs.

- *"Clinically shown to reduce stress and increase productivity"*

The Company maintained that the Evans study provided competent and reliable scientific evidence supporting an increase in productivity. More specifically, the study concluded that 28 grams of Zeal Wellness demonstrated significant improvements in overall mood and a reduction in anger-hostility in a dose-dependent, time-dependent manner compared to placebo. The Company contended that the reduction in negative mood, coupled with increased vigor-activity observed in the trial, supports the assertion that the product enhances productivity and indirectly aids in coping with stress, as endorsed by expert opinions from the World Health Organization. Additionally, Zurvita noted that the presence of caffeine and carbohydrates in the product further support the claim of "pure energy."

Zurvita stated that its testing was consistent with the Federal Trade Commission's (FTC) 2022 Health Products Compliance Guide (the "FTC Guidance"), as the product underwent a four-arm parallel, placebo-controlled, double-blind randomized clinical trial (RCT) using a validated tool for mood assessment, with statistically significant improvements observed in mood and anger-hostility.

- *"Clinically Studied: In an independent clinical study* results showed that, by drinking two servings of Zeal a day, 85% of healthy participants experienced improved overall mood and a 23% increase in vigor and activity, as well as less anxiety and fatigue."*

According to Zurvita the claim is supported by the positive response rate among participants in the clinical trial. Specifically, data from the POMS Questionnaire revealed that 85% of participants who consumed two doses of Zeal Wellness experienced an improvement in overall mood. This improvement was statistically significant compared to the placebo group, as demonstrated by the POMS total mood disturbance score. The Company asserted that the claim accurately reflects the percentage of study participants who experienced enhanced mood and completed the full 29-day trial protocol, aligning with regulatory standards and providing evidence of the product's efficacy in positively influencing mood.

Furthermore, Zurvita stated that a 23% increase in vigor and activity was based on a within-group comparison at day 29 of the participants consuming two doses of Zeal Wellness compared to baseline. Moreover, the POMS Iceberg analysis did show statistically significant improvement in anxiety and fatigue, supporting the claim of reduced anxiety and fatigue. Additionally, the Company noted that while anxiety and fatigue were not statistically significant in the regular POMS mood domain assessment, the inclusion of other statistically significant findings, such as improvements in anger-hostility from both the original POMS assessment and the POMS Iceberg analysis,

further strengthens the overall validity of the claim. Therefore, according to Zurvita, the study results corroborate the assertion in the claim regarding mood improvement, increased vigor and activity, and reduced anxiety and fatigue among participants consuming Zeal Wellness.

- *"The difference is backed by science. A study from independent third-party research firm KGK Synergize confirms that the positive benefits of drinking Zeal include improved mood, stronger vigor and vitality and less anxiety and fatigue."*

Zurvita asserted that the Evans study was administered using a rigorous scientific design and protocol and the primary outcome used a validated patient-reported outcome (PRO) tool. The Company explained that POMS measures total mood disturbance (TMD). TMD combines six mood clusters consisting of five negative mood states (Anger-Hostility, Confusion-Bewilderment, Depression-Dejection, Fatigue-Inertia, and Tension-Anxiety) and one positive mood state (Vigor-Activity). A decrease in TMD or negative mood states is indicative of an improvement in mood.

The Company pointed to the results of the Evans study as support for each improved condition:

Mood

Participants in the 2-dose-Zeal Wellness group reported a statistically significant 7.7% decrease in POMS-TMD vs. Combined Placebo at day 29 ($p = 0.047$) in the Evans study and therefore, according to Zurvita, an improvement in overall mood. Regarding specific mood states, participants in the 2-dose-Zeal Wellness group reported a statistically significant decrease of 8.6% in Anger-Hostility vs. Combined Placebo at day 29.

The Company also stated that there were also "within group" improvements in mood, which demonstrates time-dependence efficacy by Zeal Wellness and that this is an important pharmacological property to show as efficacy/benefit tends to increase over time (time-dependence), but the efficacy flattens out as maximum benefit is achieved over time. Zurvita maintained that a clinical trial should also demonstrate an increased effect with increasing dose (dose-dependence). According to the Company, both time- and dose- dependence were achieved in the Evans study.

Participants in all groups reported statistically significant improvements in POMS-TMD (overall mood score) from baseline after 29-day supplementation. The test participants who supplemented with 2-dose-Zeal Wellness reported a 23.6% improvement in POMS-TMD over baseline by day 29 while those supplemented with 1-dose-Zeal Wellness reported a 10.6% improvement over baseline by day 29. The Company asserted that these results are similar to the dose effect seen in the "intention to treat" population (i.e., all randomized participants in the analysis, whether they drop out or not). Regarding the other mood clusters, statistically significant improvements were seen in the 2-dose-Zeal Wellness group with participants reporting a decrease of 14.3% in Anger-Hostility, 19.6% in Fatigue-Inertia, 19% reduction in Confusion Bewilderment, 12.8% in Depression-Dejection, 19.4% reduction in Tension-Anxiety and an increase of 23.1% in Vigor-Activity over baseline by day 29.

Similar statistically significant improvements were seen in the 1-dose-Zeal Wellness group with participants reporting a decrease of 4.5% in Anger-Hostility, 10% reduction in Fatigue-Inertia, 12.9% in Confusion-Bewilderment, 4.9% reduction in Depression-Dejection, 12.8% reduction in Tension-Anxiety and an increase of 3.5% in Vigor-Activity over baseline by day 29.

Vigor/Vitality

According to the Company, experts agree that stress, mood, and vitality are directly linked to living a productive, functional, and fruitful life and, as such, functionality must be considered as part of the overall benefit of a product that has been demonstrated to improve patient reported outcomes in the area of mood.

Zurvita noted that in the Evans study, participants in the 2-dose-Zeal Wellness group exhibited a statistically significant increase of 19.4% in Vigor-Activity compared to the 1-dose-Zeal Wellness group by day 29, alongside statistically significant improvements of 23.1% in Vigor-Activity from baseline by the same day. As indicated by The POMS Iceberg Profile, initial baseline profiles for all participant groups demonstrated a mood state contrary to the anticipated normal profile, with a diminished peak in Vigor-Activity. Following the 29-day supplementation period, average Iceberg profiles for all groups displayed a shift, manifesting an elevation in the positive mood state of Vigor-Activity. Notably, participants in the 2-dose-Zeal Wellness group attained a favorable profile with a marked increase in Vigor-Activity, signifying a healthy state. Within the 2-dose-Zeal Wellness group there was an observed enhancement of 21.2% in vigor.

Anxiety/Fatigue

According to Zurvita, the Evans study found a statistically significant improvement in the 2-dose-Zeal Wellness group with participants reporting a decrease of 19.6% in Fatigue-Inertia. Similar statistically significant improvements were seen in the 1-dose-Zeal Wellness group with participants reporting a decrease of 10% in fatigue reduction.

Lastly, with respect to the POMS Iceberg profile, the Company noted that the Evans study reported a reduction of 17.7% in fatigue in the 2-dose-Zeal Wellness group after 29 days.

- *"Zeal has been clinically shown to reduce stress and increase productivity while making you feel vibrant, focused, calm and confident. Zeal's natural source of clean energy can provide a boost of consistent and stable, long-lasting energy throughout your day."*

The Company maintained that the double-blind, placebo-controlled randomized Evans study demonstrated that Zeal Wellness effectively reduced anger and hostility while elevating overall mood, as evidenced by statistically significant findings.

Zurvita contended that this reduction in negative mood states aligns with the World Health Organization's assertion that improved mood can enhance one's ability to cope with life stressors, thus validating Zeal's stress-reducing properties. Additionally, the Company asserted that the observed improvements in mood and the reduction in Anger-Hostility supported its claims of promoting calmness and vibrancy and reinforced the product's efficacy in enhancing emotional well-being.

The Company stated that the reference to "clean energy" is supported by Zeal Wellness' composition and mode of administration. According to Zurvita, Zeal Wellness contains multiple sources of caffeine and carbohydrate caloric content, which are recognized sources of energy. Additionally, because Zeal Wellness is designed to be consumed as two servings spaced throughout the day, it suggests a sustained release of energy, as opposed to a sudden spike followed by a crash. The Company maintained that this consumption pattern aligns with scientific knowledge regarding the metabolism of caffeine, which has a five hour half-life, and ensures a steady supply of energy throughout the day, akin to the effect of consuming caffeinated beverages intermittently over several hours. Therefore, the Company contended, the inclusion of naturally sourced caffeine and the recommended consumption pattern provide a basis for the claim that Zeal offers a consistent and stable long-lasting energy.

Zurvita noted that by comparing Zeal Wellness' caffeine content and consumption pattern to that of caffeinated coffee, it can be deduced that Zeal's energy-boosting effects can indeed be considered long-lasting if consumed as recommended.

Moreover, the inclusion of naturally sourced caffeine and carbohydrate caloric content in Zeal Wellness provides a tangible source of energy, further substantiating the claim of consistent and stable long-lasting energy throughout the day. While the exact duration of the energy boost may not have been explicitly measured in the clinical trial, the scientifically established five hour half-life of caffeine, coupled with the product's recommended consumption pattern of two servings spaced throughout the day, supports the notion of sustained energy release. Thus, Zurvita maintained that the claim of long-lasting energy is rooted in scientific understanding and aligns with the product's intended usage, making it a valid assertion supported by the provided evidence.

2. Zurvita Burn

- *"Zurvita's dietary supplement designed specifically to optimize your metabolism, and improve your strength and performance. It supports healthy blood glucose levels and helps aid in overall health and wellness. Available in a 30-day supply of 60 capsules. Zurvita supplements are essential to supporting a healthy and active lifestyle. When taken together, they work to maintain healthy bodily function, allowing you to be your best, inside and out."*

The Company stated Zeal Wellness contains 50 mcg per serving and that in accordance with Health Canada's pertinent monograph, based upon consensus opinion among experts and Health Canada, the serving level of vitamin B12 in Zurvita Burn is sufficient to support a claim that the product helps to maintain and support the body's ability to metabolize nutrients and assist with energy metabolism.

"… improves strength and performance"

As support for the assertion that Burn improves strength and performance, Zurvita provided DSSRC with a placebo-controlled, RCT of 25 healthy subjects for a 12 week duration (the "Joy study").[6] Subjects supplemented once daily with either one serving (150mg) of a proprietary blend of ancient peat and apple extract (TRT) or an equal-volume of placebo daily that was visually identical to the treatment product. Supervised resistance training consisted of eight weeks of daily undulating periodized training followed by a two week overreach[7] and a two week taper phase. Strength was determined using 1-repetition-maximum (1RM) testing in the barbell back squat, bench press (BP), and deadlift exercises. Peak power and peak velocity were determined during BP at 30% 1RM and vertical jump tests as well as a 30s Wingate test, which also provided relative power. A group x time interaction was present for squat 1RM, deadlift 1RM, and vertical jump peak power and peak velocity. Squat and deadlift 1RM increased in TRT versus placebo from pre to post. Vertical jump peak velocity increased in TRT versus placebo from pre to week ten as did vertical jump peak power, which also increased from pre to post.

Zurvita maintained that this study demonstrated that supplementing with ancient peat and apple extract while participating in periodized resistance training may enhance performance adaptations.

"… supports healthy glucose levels"

With respect to the statement that Burn supports healthy glucose levels, the Company referenced the Health Canada monograph on the DL-Alpha Lipoic Acid ingredient contained in Burn and provided several studies demonstrating the effectiveness of other ingredients in the product.

The first study[8] (the Safdar study) was an open label study aimed at investigating the effect of consumption of different amounts of cinnamon on preprandial blood glucose (PrBG), postprandial blood glucose (PoBG), glycosylated hemoglobin (HbA1c), and body mass index. According to the findings of the study, the differences between the average weight measurements, BMI values, and HbA1c values before consumption on days 20 and 40 were not statistically significant in the individuals consuming 1g, 3g, and 6g of cinnamon a day. The difference between the average PrBG measurements was found to be significant in the individuals consuming 6g of cinnamon per day. The difference between the average PoBG measurements before consumption on days 20 and 40 was significant in the individuals consuming 1g, 3g, and 6g of cinnamon daily.

A second study[9] (the Kizilaslan study) on cinnamon was submitted to DSSRC to demonstrate that cinnamon improves blood glucose levels. In this RCT study, 60 participants with type 2 diabetes (30 men and 30 women aged 52.2 ± 6.32 years) were divided randomly into six groups. Groups 1, 2, and 3 consumed 1, 3, or 6g of cinnamon daily, respectively, and groups 4, 5, and 6 were given placebo capsules corresponding to the number of capsules consumed for the three levels of cinnamon for 40 days followed by a 20-day washout period. After 40 days, all three levels of cinnamon reduced the mean fasting serum glucose (18–29%).

Zurvita stated that the results of this study demonstrate that intake of 1, 3, or 6g of cinnamon per day reduces serum glucose in people with type 2 diabetes and suggest that the inclusion of cinnamon in the diet of people with type 2 diabetes will reduce risk factors associated with diabetes and cardiovascular diseases.

To demonstrate the beneficial effects of the green coffee extract ingredient in Burn on glucose levels, Zurvita provided DSSRC with a RCT study[10] (the Patti study) conducted over a period of four months that involved 78 participants, specifically targeting individuals with metabolic syndrome.[11] The intervention comprised 160mg of Curcuma longa, 102g of silymarin, 24mg of guggul lipids, 14mg of chlorogenic acid, and 2.5mg of inulin.

According to the Company, the results demonstrated significant reductions across various parameters including body weight ($p < .0001$), body mass index ($p = .001$), waist circumference ($p = .0004$) and fasting glucose ($p = .014$).

Lastly, Zurvita submitted a placebo-controlled RCT study (the Castellino study) of 100 healthy participants with metabolic syndrome that was conducted over a period of six months to evaluate the effects of supplementation of a treatment containing chlorogenic acid and its derivatives, and luteolin and its derivatives, on cardiovascular risk and hepatic markers[12]. Anthropometric, cardiometabolic, and hepatic parameters were assessed at baseline and at the end of follow-up. According to the Company, the data indicated a significant improvement vs. placebo in most of the evaluated parameters, including body weight ($p < 0.001$), waist circumference ($p = 0.003$), HbA1c; $p < 0.001$), plasma lipids ($p < 0.001$), hepatic transaminases, flow-mediated dilation ($p < 0.001$), and carotid intima-media thickness ($p < 0.001$).

"helps aid in overall health and wellness"

As support for this claim, Zurvita provided DSSRC with a placebo-controlled RCT of 41 females with diagnosed major depressive disorder and involved supplementation of cinnamon extract for a period of eight weeks[13]. According to the Company, the statistically significant results demonstrated that symptoms of sexual dysfunction, depression, and anxiety decreased over time compared to the placebo condition.

Zurvita also referred DSSRC to the Health Canada Monograph for Cinnamon and DL-alpha-lipoic acid (DL-ALA) noting that the monograph does not provide a lower limit on Cinnamon or DL-ALA for making antioxidant claims and indicates that DL-ALA is a source of antioxidant(s). Similarly, another Health Canada Monograph for Chlorogenic acid cited by Zurvita does not provide a lower limit for making antioxidant claims.

- *"Zurvita supplements are essential to supporting a healthy and active lifestyle. When taken together, they work to maintain healthy bodily function, allowing you to be your best, inside and out."*

Zurvita contended that this statement uses fanciful language and is a term of art and rather than a claim requiring substantiation. Notwithstanding, the Company maintained that its scientific references substantiate a claim that Burn, in particular, helps to support the body's functioning (e.g., maintains glucose control).

3. Zurvita Performance R3PAIR

- *"Zurvita Performance R3PAIR is a great-tasting, berry-flavored post-workout solution that accelerates muscle recovery through premium restorative ingredients, helps to reduce muscle soreness and inflammation, while also stimulating nutrient uptake. Available in 30 servings per canister or box of 10 on-the-go stick paks.*

- *"Clinically-tested and athlete-recognized, our products are backed by award- winning ingredients, scientists, doctors and inspired by nature's best resources. And we believe in them so much, they come with a money-back guarantee."*
- *Before and after weight loss depictions*

Accelerates muscle recovery

As support for its statement that the Zurvita product accelerates muscle recovery, the Company provided DSSRC with a double-blind RCT cross-over design of 11 healthy participants for treatment with prickly pear over a four week period (the Deldicque study).[14] The study showed increased post-exercise insulin release, significant reduction in blood glucose by 7% ($P<0.05$) and the area under the 2h glucose curve by 15% ($P<0.05$), and increased serum insulin concentration at 90 minutes post exercise ($P<0.05$).

Zurvita also provided the Health Canada Monograph for Essential Amino Acids (i.e., L-Leucine), which indicated that the sufficient serving level of efficacy is a minimum of 147mg/day and that the ingredient is a source of (an) (essential) amino acid(s) involved in muscle protein synthesis.

Reduce muscle soreness and inflammation

Zurvita provided DSSRC with two studies to support its assertion that R3PAIR reduces muscle soreness and inflammation.

The first study (the Piscoya study)[15] evaluated the ability of cat's claw, an Amazonian medicinal plant, to treat osteoarthritis of the knee, collect safety and tolerance information, and compared the antioxidant and anti-inflammatory actions of Uncaria guianensis and Uncaria tomentosa in-vitro. The trial involved 45 patients with knee osteoarthritis. 30 test subjects received freeze-dried U guianensis, while 15 test subjects were administered a placebo. Throughout the four week trial, hematological parameters were monitored, and pain levels, medical assessments, and subjective evaluations were recorded weekly. The results indicated that cat's claw did not induce adverse effects on blood or liver function, with pain associated with activity significantly reduced within the first week of therapy. While knee pain at rest or at night and knee circumference were not significantly reduced, in-vitro tests suggested that cat's claw exhibited antioxidant properties and inhibited TNFalpha production, contributing to its anti-inflammatory effects.

Furthermore, the Company maintained that both U guianensis and U tomentosa species of cat's claw demonstrated equivalent efficacy in scavenging free radicals and inhibiting TNFalpha production, albeit with varying concentrations required for the latter. Although cat's claw had no effect on basal PGE2 production, it reduced LPS-induced PGE2 release at higher concentrations, further supporting its anti-inflammatory potential. Thus, Zurvita maintained, cat's claw serves as an effective treatment for osteoarthritis, attributed to its antioxidant activity and its ability to inhibit TNFalpha and PGE2 production.

The second study (the Mur study)[16] evaluated the safety and clinical efficacy of a plant extract from the pentacyclic chemotype of Uncaria tomentosa (UT) in patients with active rheumatoid arthritis (RA). 40 subjects undergoing sulfasalazine or hydroxychloroquine treatment were enrolled in a randomized 52 week, two-phase study. During the first phase (24 weeks, double blind, placebo controlled), patients were treated with UT extract or placebo. In the second phase (28 weeks) all patients received the plant extract.

According to the study results, 24 weeks of treatment with the UT extract resulted in a reduction of the number of painful joints compared to placebo (by 53.2% vs 24.1%; $p = 0.044$). Patients receiving the UT extract only during the second phase experienced a reduction in the number of painful ($p = 0.003$) and swollen joints ($p = 0.007$) and the Ritchie Index ($p = 0.004$) when compared to the results of the placebo group after 24 weeks.

According to the Company, the Mur study demonstrates the relative safety and benefit to the joint count of a highly purified extract from the pentacyclic chemotype of UT in patients with active RA taking sulfasalazine or hydroxychloroquine.

Stimulating nutrient uptake

Zurvita stated that R3PAIR contains essential amino acids, minerals, and other micronutrients that are taken up by the body. The presence of these nutrients at the brush border membrane of the intestines would stimulate their uptake from the lumen of the alimentary canal as they would be in concentrations greater in the canal lumen than what is present inside the cells. Therefore, the Company maintained, nutrient transporters would be "stimulated" to preferentially favor the shuttling of these nutrients inside the enterocytes.

4. H2O Hydrating Mix

- *"Scientifically backed"*

Zurvita asserted that the H2O Hydrating Mix contains ingredients backed by science - i.e., the product contains ingredients backed by scientific evaluation from both FDA and Health Canada.

The Company referred DSSRC to 21 CFR 101.54. This specific section of the Code of Federal Regulations pertains to "Nutrient content claims for dietary supplements" and outlines the criteria and requirements for making claims about the nutrient content of dietary supplements, including the terms and phrases that can be used to describe the level of certain nutrients in these products.

Zurvita contended that its H2O Hydrating Mix contains vitamins A and C, which have been approved by FDA for antioxidant claims. Antioxidants are ingredients known and tested scientifically to have oxygen radical absorbance capacity with the ability to scavenge free radicals in the body.

Zurvita also maintained that the claim was supported by four Health Canada monographs.

The Health Canada monograph for Vitamin C indicates that a minimum dose of 6mg per day contains a sufficient serving level to support the monograph claim that the ingredient helps to maintain/support the body's ability to metabolize nutrients.

In the Health Canada monograph for Pantothenic Acid, it is stated that a sufficient minimum level is 0.4mg/day and that the H2O Hydrating Mix contains a sufficient level of the ingredient to support monograph claims that the ingredient helps in energy metabolism and helps to maintain/support the body's ability to metabolize nutrients.

The Health Canada monograph for Vitamin B2 outlines several health benefits associated with its consumption. According to the Company, the amount of Vitamin B2 found in its H20 mix contains a sufficient serving level to support monograph claims regarding the ingredient's role in energy metabolism and tissue formation, healthy mucous membranes, and maintaining normal red blood cells. Zurvita additionally noted that Vitamin B2 aids in the metabolism of iron and supports the body's ability to metabolize various nutrients, indicating its importance for overall health and well-being.

Lastly, pursuant to the Health Canada monograph for Vitamin B1, Zurvita's H20 mix contains a sufficient serving level of Vitamin B1 to state that the product "helps in energy production."

5. Recovery Essentials System (Zundora/R3PAIR/H2O Hydrating Mix)

- *"This wonderful bundle is designed to accelerate muscle recovery, boost hydration levels, and support healthy skin, hair, nails, and joint mobility. It is the first step to preparing your body for peak performance by supporting your muscles and joints with nutrient-dense ingredients that are clinically clean and effective and keep you hydrated."*

According to Zurvita, the H2O hydration mix offers hydration on the basis of consumption of the powder mix in water and, by definition, drinking water will provide hydration.

The Company asserted that the effectiveness of its products in reducing joint pain had already been addressed in the studies submitted to DSSRC as evidence supporting the claims that its R3PAIR product reduces muscle soreness and inflammation.[17]

ANALYSIS

During the pendency of the inquiry, in the spirit of self-regulation, Zurvita removed and revised a number of claims that were the subject of the challenge. As such, DSSRC limited its review to the remaining product claims at issue. DSSRC appreciated the Company's good faith efforts to voluntarily address its concerns and agreed that Zurvita's actions were necessary and appropriate.

1. Zeal Wellness

Zurvita's evidentiary basis for the establishment claims communicated on the Company's website was the Evans study - a 2017 clinical study involving 100 participants.[18]

As DSSRC has noted in previous self-regulatory inquiries, claims that a product or ingredient is "clinically" or "scientifically" proven provides a very strong message to consumers. RCTs represent the most reliable form of evidence and are typically the type of substantiation that experts would seek for health benefit claims.

The Evans Study

Under FTC law, advertisers must have a reasonable basis for their product claims before disseminating an ad. The FTC's substantiation standard is a rigorous one, particularly when claims relate to health. With respect to assertions regarding the effectiveness or safety of

health-related products, the FTC requires "competent and reliable scientific evidence" to support such claims. The FTC has further delineated this standard as comprising "tests, analyses, research, or studies that (1) have been conducted and assessed objectively by experts in the pertinent disease, condition, or function to which the assertion pertains, and (2) are generally recognized within the profession to produce accurate and dependable outcomes."[19]

DSSRC agreed with Zurvita that the Evans study provided valuable preliminary data regarding the potential health benefits achievable through the directed use of Zeal Wellness. Specifically, the Evans study, designed as a randomized, double-blind, placebo-controlled clinical trial, yielded statistically significant results across several primary endpoints. Although the NGO raised concerns about the self-reporting methodology (POMS) utilized by the study administrators to gauge the mood states of the participants, DSSRC did not share these concerns regarding the validity of this self-reporting tool. POMS, recognized as a validated and widely adopted questionnaire for assessing transient or enduring mood states, is commonly employed in clinical research to evaluate the benefits of an intervention or the risks associated with adverse events. Within clinical trials, a Patient Reported Outcome (PRO) questionnaire, such as POMS, serves to gauge the impact of a medical intervention on various concepts, including symptoms. A PRO captures any health-related status report directly from the participant, without interpretation by a clinician, investigator, or any other intermediary and use of a PRO instrument is even advised when measuring a concept best known and understood by the patient or best measured from the patient's perspective.

Accordingly, while acknowledging that the foundational methodology of the Evans study did fulfill several of the FTC's criteria for a credible clinical study, DSSRC nevertheless had several reservations regarding the reliability of this one study to substantiate the establishment (i.e., clinically proven) claims communicated by Zurvita.

More specifically, although the FTC does not require a specific number of RCTs, duplicating research in a study conducted independently further corroborates the strength of the evidence. When a second study, carried out by independent researchers, replicates the findings, it diminishes the likelihood of potential biases that may arise unexpectedly and go unnoticed, despite the best efforts of sponsors and investigators. An additional, an independently conducted study to substantiate the initial findings instills significantly greater confidence in their validity.[20]

Below are several representative establishment claims that the Company communicated based upon the results of the Evans study:

- "Clinically shown to reduce stress and increase productivity"
- "Clinically Studied: In an independent clinical study* results showed that, by drinking two servings of Zeal a day, 85% of healthy participants experienced improved overall mood and a 23% increase in vigor and activity, as well as less anxiety and fatigue."
- "The difference is backed by science. A study from independent third-party research firm KGK Synergize confirms that the positive benefits of drinking Zeal include improved mood, stronger vigor and vitality and less anxiety and fatigue."
- "Zeal has been clinically shown to reduce stress and increase productivity while making you feel vibrant, focused, calm and confident. Zeal's natural source of clean energy can provide a boost of consistent and stable, long-lasting energy throughout your day."

The Evans study involved 99 participants in its clinical trial. DSSRC expressed concern that the study's sample size might not have been sufficiently large enough to detect smaller, yet potentially important, effects. This concern was amplified by the fact that the group to which the "clinically proven" results were relevant consisted solely of the 24 participants who received the treatment twice daily and provided self-reported responses. While self-assessment scores can be appropriate in clinical studies, depending on the context and objectives of the research, the use of such data must be carefully considered and complemented by other objective measures to ensure a well-rounded and accurate understanding of the research outcomes.

DSSRC also had reservations regarding the decision of the study administrators to combine the placebo groups in its statistical analysis to gain additional power because, according to the Company, the covariate was found not to be significant. While DSSRC recognizes the test administrators' rationale for combining the placebo groups (i.e., to yield a larger sample size for its analysis), it was also concerned that the decision to combine the placebo groups did not align with the original protocol and design of the study to have separate placebo groups for different treatment arms (i.e., daily administration of one dose and two doses). If there were substantial differences between the placebo groups that could impact outcomes, combining them may not be appropriate. Accordingly, one potentially significant difference between placebo groups was the reported stress levels. The placebo groups in the Evan study had significantly higher stress levels than the intervention groups at baseline ($p = 0.018$). In addition, a comparison of the placebo groups with the 2-dose Zeal group, resulted in a sample size that consisted of 61% (46 of 75 test participants) women.[21] This discrepancy in the gender of the test participants could potentially skew the data as women may have different results from taking a wellness drink as compared to men due to several physiological, hormonal, and metabolic differences between the sexes. For example, metabolic rates and pathways can differ between men and women, affecting how ingredients in a wellness drink are absorbed, distributed, metabolized, and excreted. Similarly, differences in body composition, such as muscle mass and fat distribution, can influence how nutrients and other active ingredients in a wellness drink are utilized in the body and psychological responses to stress and mood disorders can vary between men and women due to both biological and social factors, possibly leading to different outcomes from consuming a wellness drink.

DSSRC also noted that the Evans study did not provide sufficient information on participants' overall lifestyle, diet, and activity levels. Notably, there is no description provided in the study of the dietary intake, supplement use, exercise activity, and/or vitamins/minerals for the subjects (before, during, and after the study). In research aimed at assessing changes in mood, stress, and vitality, DSSRC determined

that such background information is essential for drawing definitive conclusions. Because lifestyle, diet, and activity levels can significantly influence mood, stress, and vitality, without accounting for these factors, it is difficult to determine whether observed changes are due to the intervention or these underlying variables. As such, DSSRC determined that ensuring that participants have similar lifestyle, diet, and activity levels at baseline helps to confirm that any differences observed at the end of the study are due to the intervention rather than pre-existing differences between participants.

DSSRC also notes that the study administrators specifically discuss the limitations of the study, stating that "Future studies should consider determining the status of vitamins and other nutrients in participants to compare the effect of the beverage with pre-supplementation/baseline vitamin and nutrient values. Determining salivary or serum cortisol levels as an adjunct and complementary marker of mood states and an increase in the sample size to allow for better expression of between-group differences in the parameters that displayed trends toward significance would be of value."[22]

Moreover, in assessing the reliability of this one study to support the establishment claims at issue, DSSRC also considered that two of the study administrators were part of the Scientific Advisory Board for Zurvita. While this is not necessarily a fatal flaw regarding the study, it was an additional factor in the assessment of the overall reliability of this particular study to support the establishment claims.

Zurvita's expert also agreed that the study results did not support several of the claims at issue in their original context. For example, the Company's expert did not agree that the study supported the quantified claim of "23% increase in vigor and activity" noting that "[t]here was a clear dose-dependent effect as the 1-dose-Zeal Wellness effect was indistinguishable from placebo in all POMS mood domains." The expert also suggested that the claim stating "85% of healthy participants experienced a variety of positive results … just within 29 days – including decrease in fatigue, anxiety and a 23% increase in vigor and activity!" be revised to replace references to anxiety and fatigue, which were not found to be statistically significant in the regular POMS mood domain assessment. With respect to the reference to decreasing "confusion" (i.e., "Zeal has been clinically shown to improve mood, give you stronger vigor and vitality, and decrease your anxiety, fatigue, anger and confusion.") the expert stated that he did not believe that "a reduction in confusion is substantiated."

DSSRC did not agree with the Company's expert that Zurvita adequately supported the claim that Zeal Wellness has been "clinically shown to … increase productivity." According to the expert "[p]roductivity has been increased based on indirect evidence from World Health Organization experts, who have stated that elevated mood enhances overall functioning and productivity." The Company maintained that this is further supported by the results of the POMS Iceberg profile used in the Evans study. Specifically, the Company asserted that the study results demonstrated that participants in the 2-dose-Zeal Wellness group achieved a healthy profile with a significant peak in the positive mood state of Vigor-Activity. Additionally, the 2-dose-Zeal Wellness group showed a statistically significant improvement over the 1-dose-Zeal Wellness group in the POMS positive mood domain of Vigor-Activity.[23]

Notwithstanding the expert's interpretation of the study results, DSSRC concluded that support for an establishment claim should be based on the results of attributes that have been clinically validated in the testing and not by "indirect" evidence from third-party entities. Moreover, any references to clinically proven outcomes that were not directly assessed (e.g., focus and/or functionality) should not be based on generalizations about how those conditions might be part of, or related to, a specific state (e.g., overall mood).

While DSSRC acknowledged that the Evans study produced encouraging results and that Zurvita could discuss these results as long as the study's limitations are carefully conveyed and if the study results are not presented in a context that could be interpreted as being "clinically proven," DSSRC also concluded that the Evans study, alone, did not sufficiently support the establishment claims under review. Therefore, DSSRC recommended that Zurvita discontinue or modify these claims.

1. Zurvita Burn

An advertiser has the burden to support any reasonable interpretations of its claims.[24] The product page on the Company website describes Zurvita Burn as "designed specifically to optimize your metabolism and improve your strength and performance. It supports healthy blood glucose levels and helps aid in overall health and wellness." DSSRC determined that the claim communicated three specific benefits for Zurvita Burn that necessitated evidentiary support.

"designed specifically to optimize your metabolism"

First, DSSRC concluded that the claim that the product was "designed specifically to optimize your metabolism" could be reasonably interpreted in a literal context – i.e., that the directed use of Zurvita Burn will improve the efficiency of the body's metabolic processes. The Company cited to a Health Canada Monograph for the Vitamin B-12 as support for the claim and noted that the monograph permits a claim that the amount of Vitamin B-12 in Zurvita Burn "helps to maintain/support the body's ability to metabolize nutrients." While DSSRC agreed that the reference to the Health Canada monograph was helpful, it was also determined that the monograph, by itself, was not sufficient to support the claim in the context stated in the online description of Zurvita Burn.[25]

Even assuming arguendo that the Health Canada monograph was dispositive on the adequacy of a claim that 50 mcg of Vitamin B-12 "helps to maintain/support the body's ability to metabolize ingredients," the claim now before DSSRC is can be distinguished from the

language authorized by Health Canada as DSSRC determined that a claim to "optimize" metabolism would require evidence that an individuals' metabolism is *improved* by 50 mcg of Vitamin B and not simply maintained. In the absence of such evidence, DSSRC determined that the claim stating that Zurvita Burn is "designed specifically to optimize your metabolism" has not been adequately substantiated and recommends that the Company modify the statement.

"improve your strength and performance"

The Company did not submit testing on the product itself but, instead, provided DSSRC with a study on a formulation of the ancient peat and apple extract contained in Zurvita Burn.

DSSRC determined that the Joy study, which evaluated the effects of a 150mg of a proprietary blend of ancient peat and apple extract on 25 subjects over a 12 week period was not sufficient to support the claim that Zurvita improves strength and performance.

More specifically, as support for the assertion that Burn improves strength and performance, Zurvita provided DSSRC with a placebo-controlled, RCT of 25 healthy subjects for a 12 week duration (the "Joy study").[26] Zurvita maintained that this study demonstrated that supplementing with ancient peat and apple extract while participating in periodized resistance training may enhance performance adaptations. Although Zurvita is targeted to both men and women, the study was conducted on 25 resistance-trained male subjects and was of limited size (i.e., 14 subjects in the treatment group). As noted in the FTC Guidance, advertisers should avoid basing claims aimed at the general population solely on research conducted with a specific test group unless it's scientifically justified to do so. It is further noted in the Guidance that one aspect of evaluating the reliability of the study involves ensuring that the demographics of the study population align with those targeted by the advertisement.[27] Additionally, the FTC Guidance cautions advertisers on whether it's suitable to generalize the research findings to the claimed effect.[28]

Lastly, DSSRC could not confirm whether the increases in lower body and total strength of test subjects over the 12 week test period were attributable to the daily resistance training that was performed by the test subjects rather than the treatment and whether similar results would be observed in non-resistance trained subjects.

Accordingly, DSSRC recommended that Zurvita modify or discontinue its claim that Zurvita Burn will improve an individual's strength and performance.

Supports healthy blood glucose levels

The Company relied on testing of several individual ingredients in Zurvita (i.e., DL-Alpha Lipoic Acid, cinnamon, green tea, and chlorogenic acid) as support for its claim that the product supports healthy blood glucose levels.

DSSRC agrees that research on these ingredients has demonstrated that each of the ingredients observed, individually, may have a beneficial effect on blood glucose levels. However, DSSRC also notes that the studies provided by Zurvita as support for the claim either tested the ingredient at different levels than it is present in the product or, alternatively, examined the pure ingredient rather than the extract form present in the product. For example, Zurvita Burn contains 15mg of cinnamon concentrated extract 4:1 (Cinannamomum Cassia) (Bark). However, both the Kizilaslan and Safdar studies observed the effects of 1g, 3g, and 6g of cinnamon (i.e., significantly greater than the cinnamon extract present in Zurvita Burn).[29] The Safdar study also tested a population of subjects with type 2 diabetes, which represents only one potential segment of the product's target audience.

Zurvita Burn also contains 50mg of green tea extract from camillia sinensis and 50mg of green tea that is 50% chlorogenic acids. The Company provided DSSRC with one study that observed the effects of 14mg of chlorogenic acid which was combined into one pill with Curcuma Longa, silymarin, guggul lipids and inulin. However, the authors noted the limitations of the data noting that the research was considered only a pilot study and that the study lacked a control (placebo) group as well as the coadministration of several drugs for prevention of cardiovascular disease. As such, in addition to these study limitations, DSSRC could not reliably ascertain the role of the chlorogenic acid in the positive results reported in the study and determine how that ingredient was comparable to the green tea extract contained in Zurvita Burn.

Similarly, in the Castellino study a 150mg supplement containing 10–12% chlorogenic acid and derivates and 2–4% luteolin-7-glucoside and derivates was administered to test subjects. Although the results did indicate that there was a significant improvement in glucose metabolism parameters in the test group, the presence of chlorogenic acid in the test supplement was of a different amount than as contained in Zurvita Burn, the additional ingredients in the studied supplement were considerably different than those ingredients in Zurvita Burn, and the resulting interaction of chlorogenic acid with the Zurvita Burn ingredients may not provide similar results.

In conclusion, DSSRC determined that the Company's evidence did not reliably support the claim of supporting healthy blood glucose levels.

3. Zurvita Performance R3PAIR

- *Accelerates muscle recovery*

DSSRC recognized that the Deldicque study provided by Zurvita to support the claim that Performance R3PAIR accelerates muscle recovery was randomized, double-blinded, and placebo controlled. However, despite the cross-over methodology employed in the test, the study size was particularly small (11 subjects), the test subjects were all male endurance athletes, and subjects had a very controlled diet (that included fasting until the next morning before exercising). The study results did indicate that *Opuntia ficus-indica* (i.e., prickly pear) does have an additive insulinogenic effect, but the data was limited to a very specific demographic (i.e., male endurance athletes) and it could not be determined whether the data would be applicable to the remaining appreciable segment of R3PAIR's target audience.[30]

As noted by the test administrators, "Further studies should try to determine whether the higher circulating insulin levels established by combined OFI plus leucine administration together with high-rate glucose uptake post exercise, effectively translate into higher glycogen synthase activity and glycogen resynthesis rate following exercise."

In sum, DSSRC determined that while the Deldicque study results were encouraging, the test could not be solely relied on as adequate support for the claim that R3PAIR accelerates muscle recovery.

As also noted in the previous section of DSSRC's analysis pertaining to Zeal Wellness, reference to a Health Canada monograph would not be considered dispositive regarding claims disseminated in the United States and how those claims are regulated. Thus, it was determined the advertiser's reliance on Health Canada's monograph regarding L-Leucine did not provide adequate support for a claim that R3PAIR accelerates muscle repair.

Helps to reduce muscle soreness and inflammation

As support for the claim that R3PAIR helps to reduce muscle soreness and inflammation, Zurvita provided DSSRC with two studies, the Piscoya study and the Mur study.

The Piscoya study[31] evaluated the ability of cat's claw (*U. guianensis*) to treat osteoarthritis of the knee on 45 subjects. Similar to DSSRC's discussion of the Joy study provided to support the Company's claims for Zurvita Burn, although R3PAIR is marketed to a general audience, the study was conducted solely on male subjects.

DSSRC also had reservations regarding the applicability of the test data to R3PAIR because of the study's relatively small sample size (45 subjects) and the route of administration of the treatment product (capsule) in the study, which was different than how the R3PAIR drink mix is to be consumed. DSSRC also noted that the ingredient in the study was administered in a freeze-dried form, which assists in preserving the ingredient's original properties including its nutritional content and structure.

While DSSRC recognized that pain associated with activity, medical, and patient assessment scores were all significantly reduced in the treatment group, the study administrators noted that knee pain at rest or at night and knee circumference were not significantly reduced by cat's claw. Moreover, DSSRC concluded that a general claim of "reduced soreness and inflammation" was not reliably supported by showing reduced inflammation in one location of the body (i.e., the knee). The way an ingredient reduces inflammation may vary depending on the part of the body due to variations in absorption rates and the specific inflammatory pathways present. Different tissues and organs have distinct inflammatory pathways and responses, which can influence the effectiveness of the ingredient and the distribution of an ingredient throughout the body can vary. Some ingredients may accumulate more in certain tissues, affecting their ability to reduce inflammation in other areas.

Lastly, the dosage of the treatment product (100mg) to test subjects was significantly lower than the recommended dosage of the cat's claw ingredient as contained in R3PAIR (300mg). DSSRC notes that the relationship between dose and efficacy is not always linear. Sometimes, increasing the dose beyond a certain point may not increase the efficacy and could even reduce it. Each ingredient may have an optimal dose range where it is most effective. Beyond this range, increasing the dose might not provide additional benefits and could even lead to diminished returns or adverse effects.

Similarly, the Mur study[32] was described as a small preliminary study conducted in 2002 that involved 40 subjects undergoing sulfasalazine or hydroxychloroquine treatment. It was also noted in the study that Nonsteroidal anti-inflammatory drugs (NSAID) and prednisolone up to 10mg/day or its equivalent were permitted. Accordingly, DSSRC was uncertain if the efficacy observed in the study was due to the test product or whether the concurrent treatments contributed to the positive results. As in the Piscoya study (discussed above), the treatment product was administered in capsule form, which is a different form of administration from the R3PAIR drink mix.

Lastly, the Company did not explain how the 20mg of an aqueous acid-extracted dry extract of Radix Uncariae tomentosae used in the test product was equivalent to the similar ingredient that is present in R3PAIR.

For all of the aforementioned reasons, DSSRC determined that the Company's testing, although encouraging, did not provide adequate substantiation that R3PAIR helps reduce muscle soreness and inflammation.

Stimulating nutrient uptake

Zurvita demonstrated that R3PAIR contains important nutrients like amino acids and minerals that the body can absorb. When these nutrients are present in the intestines, they encourage the body to absorb more from the digestive tract which makes the body's nutrient transporters more active in bringing these nutrients into the intestinal cells.

DSSRC concluded that the product's resulting increase in nutrient absorption provided a reasonable basis for the statement that R3PAIR stimulates nutrient uptake.

"Clinically- tested and athlete- recognized, our products are backed by award- winning ingredients, scientists, doctors and inspired by nature's best resources. And we believe in them so much, they come with a money-back guarantee."

With respect to Zurvita's claim that R3PAIR is "Clinically Tested," this is a type of establishment claim which is held to a very high standard of proof because it is, in essence, a promise that there is scientific evidence that proves or "establishes" the truth of an advertiser's claim.[33] As a general rule, because of the weight that these types of claims carry, advertising self-regulatory programs administered by BBB National Programs have consistently held that they must be supported by competent and reliable scientific testing on the actual products advertised, and not simply the ingredients therein.[34]

Although DSSRC determined that the "clinically tested" claim could be reasonably interpreted by consumers as meaning that the R3PAIR product itself was clinically tested[35], the Company did not provide DSSRC with testing on the marketed product and, as noted earlier, it was determined that the ingredient testing provided by Zurvita would not meet the reliable and competent scientific evidence standard required to support an establishment claim.

As such, DSSRC recommended that the Company modify or discontinue its claim that R3PAIR has been "clinically tested."

Before and after weight loss depictions

The Company removed depictions of atypical weight loss from both the Company website and from YouTube.

DSSRC appreciated the Company's voluntary efforts and determined that this action was necessary and appropriate.

4. H2O Hydrating Mix

- *"A scientifically-backed drink mix that will hydrate you faster and more effectively"*

On the Zurvita website, the Company describes its H2O Hydrating mix as a "scientifically-backed drink mix that will hydrate you faster and more effectively." Zurvita based its "scientifically backed" claim on Health Canada monographs for Vitamin C, Pantothenic Acid, Vitamin B1, and Vitamin B2, all ingredients contained in Zurvita's H2O Hydrating mix.

Preliminarily, DSSRC determined that it would not be unreasonable for consumers to interpret the "scientifically backed" claim to mean that the product itself had undergone scientific scrutiny rather than certain ingredients in the product. However, there has been no testing provided by the Company on the H20 Hydrating Mix and, instead, Zurvita relied on monograph language from Health Canada to support the claim. The Company also stated that Vitamins A and C have been approved by the FDA for antioxidant claims and that antioxidants are ingredients known and scientifically tested to have oxygen radical absorbance capacity with the ability to scavenge free radicals in the body.

Here, DSSRC concluded that consumers would reasonably expect the claim to be backed by direct evidence and that the Company did not meet its evidentiary burden to support the claim by simply showing that antioxidants support overall health indirectly.

More specifically, while DSSRC does not dispute the antioxidant capacity of certain ingredients in Zurvita's H20 Hydrating Mix, it also noted that the Company did not provide evidence showing how these antioxidants directly hydrate the body. As such, it was determined that a claim implying that a product is "scientifically backed" to hydrate an individual "faster and more effectively" was not adequately supported solely by maintaining that five of 13 ingredients in the product are present at such a level in the H20 Mix to support monograph claims that do not directly correlate to hydration.

DSSRC was also troubled by the presence of only 0.8mg of pantothenic acid in one serving size of Zurvita's H20 Hydrating Mix although the Canada Health monograph stipulates that a minimum level of 0.4mg per day of pantothenic acid is needed to support the monograph claims.[36] In addition, according to the FDA, while the H20 Hydrating Mix has a daily amount of 75mcg of Vitamin A per serving, the recommended daily amount of vitamin A is 900mcg for adult men and 700mcg for adult women and the recommended daily amount of Vitamin A. Similarly, the FDA recommended daily value for Vitamin B1 (thiamin) is 1.2mg and 1.3mg for Vitamin B2 (riboflavin). Conversely, the H20 Hydrating Mix contains only 0.1mg of Vitamin B1 (thiamin) and 0.2mg of Vitamin B (riboflavin).

Moreover, as DSSRC has noted earlier in its analysis, while reference to a Health Canada monograph is helpful, reference to the monograph, by itself, was not sufficient to support the claim in the context stated in an online product description.

DSSRC recommended that Zurvita discontinue its "scientifically backed" reference in the context presented to describe the H20 Hydrating Mix and should Zurvita consider similar language in future advertising, it is recommended that language reference "scientifically backed ingredients" so as not to imply that the marketed product itself has been clinically scrutinized. In addition, any reference to ingredients that are scientifically backed should specify the precise clinical outcome (e.g., energy metabolism) to which it pertains.

5. Zundora

- *"Clinically proven to provide healthier-looking hair, skin and nails. Zundora can reduce the appearance of fine lines and wrinkles in just 28 days for your beauty on the outside."*

The Company conceded that it did not possess substantiation for Zundora's effects on hair and nails and that 28 days should not be promoted as the earliest period for which benefits can be expected. Accordingly, DSSRC concluded that such language should be discontinued.

With respect to claims pertaining to skin, the Company provided eight studies on the effect of certain ingredients present in Zundora (i.e., lumenato tomato, hydrolyzed collagen, hyaluronic acid). However, none of the studies observed the ingredients when administered orally in a liquid gel pack (as Zundora is directed to be used) but rather the ingredients were administered during the study in capsule form. Moreover, almost all of the studies were conducted only on women and several of the studies indicated that there were no significant results observed after 28 days. Lastly, several of the ingredients in Zundora are combined in a proprietary "Beauty from Within Blend" and DSSRC was not provided with a specific ingredient breakdown of the proprietary formula.

DSSRC noted that several of the studies on collagen provided by Zurvita were conducted on women and did result in reliable, statistically significant data that the Company could utilize in future advertising if presented in the appropriate context. Nonetheless DSSRC concluded that the establishment claim regarding the benefits of Zundora was not substantiated in the context presented on the Zurvita website and should be discontinued or modified accordingly.

6. Recovery Essentials System (Zundora/R3PAIR/H2O Hydrating Mix

"This wonderful bundle is designed to accelerate muscle recovery, boost hydration levels, and support healthy skin, hair, nails, and joint mobility. It is the first step to preparing your body for peak performance by supporting your muscles and joints with nutrient-dense ingredients that are clinically clean and effective and keep you hydrated."

Zurvita did not provide any data regarding how the three products in its Recovery Essentials System would interact or if the efficacy of one product may be offset by the presence of another. While DSSRC did not object to general claims about boosting hydration as the products are consumed with water, our concerns regarding the studies provided by Zurvita to support joint related claims for R3PAIR were discussed in that section of this analysis – i.e., relatively small sample size in the testing, only female test subjects, the route of administration of the product being different from the treatment product used in the study, and the evaluation of ingredient efficacy in isolated areas of the body. Moreover, DSSRC has determined that claims relating to several alleged benefits of Zundora (e.g., healthier hair and nails) were not supported.

DSSRC was unsure what was meant by Zurvita's reference to "clinically clean" ingredients as the term is not a precise scientific term. If the Company intended to describe the purity standard of its ingredients or if the term was intended to convey compliance with good manufacturing practices, it is recommended that the Company characterize the standard of its ingredients more clearly in future advertising.

For the above reasons, DSSRC recommended that Zurvita modify or discontinue the claim pertaining to its Recovery Essentials System.

Conclusion

During the pendency of the inquiry, Zurvita removed and revised a number of claims that were the subject of the challenge. As such, DSSRC limited its review to the remaining product claims at issue. DSSRC appreciated the Company's good faith efforts to voluntarily address its concerns and agreed that Zurvita's actions were necessary and appropriate.

While acknowledging that the Company's testing on Zeal Wellness produced encouraging results, DSSRC also concluded that the one study, alone, did not sufficiently support the establishment claims at issue and recommended that Zurvita discontinue or modify such claims.

DSSRC determined that the claims stating that Zurvita Burn "is designed specifically to optimize your metabolism," "improves your strength and performance," and "supports health blood glucose levels" have not been adequately substantiated and recommended that the Company modify the claims.

Regarding Zurvita's R3PAIR, it was concluded that while the Company's study results were encouraging, the testing could not be solely relied on as adequate support for the claim that R3PAIR accelerates muscle recovery. DSSRC also determined that the advertiser's reliance on Health Canada's monograph regarding L-Leucine did not provide adequate support for a claim that R3PAIR accelerates muscle repair and that the Company's testing, while encouraging, did not provide adequate substantiation that R3PAIR helps reduce muscle soreness and inflammation. DSSRC concluded that the product's resulting increase in nutrient absorption provided a reasonable basis for the statement that R3PAIR stimulates nutrient uptake.

DSSRC recommended that Zurvita either discontinue its "scientifically backed" reference in the context presented to describe the H20 Hydrating Mix and should Zurvita consider similar language in future advertising, it is recommended that it limit the use of the language to "scientifically backed ingredients" so as not to imply that the product itself has been clinically scrutinized.

The Company conceded that it did not possess substantiation for Zundora's effects on hair and nails and that 28 days should not be promoted as the earliest period for which benefits can be expected. Accordingly, DSSRC concluded that the establishment claim regarding the benefits of Zundora was not substantiated in the context presented on the Zurvita website and should be discontinued or modified accordingly.

Lastly, Zurvita did not provide any data regarding how the three products in its Recovery Essentials System would interact or if the efficacy of one product may be offset by the presence of another. While DSSRC did not object to general claims about boosting hydration, it was recommended that Zurvita modify or discontinue the specific performance claims pertaining to its Recovery Essentials System. It was also recommended that the Company provide more information in its description of the "clinically clean" ingredients in its Recovery Essentials System.

Company Statement

"Zurvita is a proud member of the Direct Selling Association and appreciates the DSSRC's commitment to industry excellence. Zurvita welcomed the opportunity to work closely with the DSSRC team to provide substantiation for identified claims and to modify or remove claims that lacked proper substantiation. Zurvita is committed to full compliance with the DSSRC's recommendations. Please know that Zurvita takes all compliance matters very seriously. Since its incorporation in 2008, Zurvita has hired the most qualified employees in its Compliance and Legal Departments who leverage industry leading software to educate, train and monitor Zurvita's staff and independent sales associates for compliance. Zurvita aggressively and immediately responded to the DSSRC's concerns regarding identified claims and continues to improve, modify, or remove non-compliant claims. Zurvita is wholly committed to attaining and maintaining its goal of 100% compliance. We, at Zurvita, greatly respect the work of the DSA and the DSSRC and appreciate the ongoing education and guidance it provides to Zurvita and to the direct sales industry."

(Case #167, closed on 06/25/24)

[1] The Better Business Bureau located in Dallas, Texas.

[2] Evans, M., Antony, J., Guthrie, N., Landes, B., & Aruoma, O. I. (2018). A Randomized Double-Blind, Placebo Controlled, Four-Arm Parallel Study Investigating the Effect of a Broad-Spectrum Wellness Beverage on Mood State in Healthy, Moderately Stressed Adults. *Journal of the American College of Nutrition*, *37*(3), 234–242. https://doi.org/10.1080/07315724.2017.1393356.

[3] Zurvita recommends consuming Zeal Wellness twice daily for optimal benefits. Typically, this involves taking one scoop (14 grams) mixed with 6-8 ounces of water or a preferred beverage, twice a day.

[4] The POMS (Profile of Mood States) Iceberg Analysis is a method used to assess mood states beyond the traditional measures provided by the standard POMS questionnaire. The POMS questionnaire is a psychological assessment tool that evaluates various mood states such as tension, depression, anger, vigor, fatigue, and confusion. The Iceberg Analysis extends this assessment by examining additional dimensions of mood and behavior, providing a more comprehensive understanding of emotional well-being.

[5] The expert's responsibilities also include aligning study endpoints and designs with structure function claims desired by sponsors, offering advice on novel study designs, and ensuring studies meet regulatory goals within client budgets. Previously, he held the role of Senior Vice President for Scientific and Regulatory Affairs at the Natural Products Association and addressed compliance failures in dietary supplement manufacturing practices and labeling regulations.

[6] Joy JM, Vogel RM, Moon JR, Falcone PH, Mosman MM, Pietrzkowski Z, Reyes T, Kim MP. Ancient peat and apple extracts supplementation may improve strength and power adaptations in resistance trained men. BMC Complement Altern Med. 2016 Jul 18;16:224. doi: 10.1186/s12906-016-1222-x. PMID: 27430755; PMCID: PMC4950767.

[7] The goal of an *overreaching* phase is to impose a very large amount of stress in your body through *training* and then immediately enter a recovery phase.

[8] Kizilaslan N, Erdem NZ. The Effect of Different Amounts of Cinnamon Consumption on Blood Glucose in Healthy Adult Individuals. Int J Food Sci. 2019 Mar 4;2019:4138534. doi: 10.1155/2019/4138534. PMID: 30949494; PMCID: PMC6425402.

[9] Khan A, Safdar M, Ali Khan MM, Khattak KN, Anderson RA. Cinnamon improves glucose and lipids of people with type 2 diabetes. Diabetes Care. 2003 Dec;26(12):3215-8. doi: 10.2337/diacare.26.12.3215. PMID: 14633804.

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[11] Zurvita noted that according to FDA policy outlined in the January 6, 2000 structure function final rule, metabolic syndrome is not categorized as a diseased population; instead, it's considered within the spectrum of a healthy population.

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Format:

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[17] *Supra* at 15 and 16.

[18] *Supra* at 2.

19 See FTC Health Product Compliance Guidance at https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf at page 12.

[20] *Id* at page 13.

[21] *Supra* at 2. There appeared to be a mistype in Table 1 of the published study which mistakenly refers the demographics and characterizations of the 2-Dose Zeal Wellness group as pertaining to the "1-Dose Zeal Wellness" group.

[22] *Id* at page 241.

[23] DSSRC also noted that the applicability of the research findings often depends on the audience to whom the advertising is targeted. To apply the conclusions to a global audience, participants should ideally be selected from various centers (urban and rural) across the entire geographical area. Here, the Evans study was conducted in one location – i.e., the KGK Science Clinical Trial Center in Orlando, Florida.

[24] *See* 1984 FTC Policy Statement Regarding Advertising Substantiation - https://www.ftc.gov/legal-library/browse/ftc-policy-statement-regarding-advertising-substantiation Appended to Thompson Medical Co., 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987).

[25] As noted by the National Advertising Division (a sister program to DSSRC also administered by BBB National Programs) in a case involving doTERRA essential oils where the advertiser cited to the fact that Health Canada established a monograph for essential oils' use in aromatherapy, "[e]ven when claims are addressed by foreign regulatory or self-regulatory agencies, NAD must evaluate the evidence presented independently." *See* doTERRA International, LLC (doTERRA Essential Oils), Report #6420, *NAD/CARU Case Reports* (October 2020).

[26] Joy JM, Vogel RM, Moon JR, Falcone PH, Mosman MM, Pietrzkowski Z, Reyes T, Kim MP. Ancient peat and apple extracts supplementation may improve strength and power adaptations in resistance trained men. BMC Complement Altern Med. 2016 Jul 18;16:224. doi: 10.1186/s12906-016-1222-x. PMID: 27430755; PMCID: PMC4950767.

[27] *Supra* at 19. Page 23.

[28] *Id* at 24.

[29] *Supra* at 5. The Kizilaslan study noted specifically that "[s]tudies have shown that ground cinnamon is more effective than its extract. It has been reported in clinical studies that Chinese cinnamon is more effective than Ceylon cinnamon."

[30] DSSRC noted that the group who were administered the *Opuntia ficus-indica* ingredient combined with leucine (another ingredient contained in R3PAIR) had better results although the amount of leucine included in the treatment was of a considerably greater amount than the amount of leucine that is present in R3PAIR.

[31] *Supra* at 15.

[32] *Supra* at 16.

[33] See, e.g., Patent Health, LLC (Fluid Joint Dietary Supplement for Joint Function), Report #4335, NAD Case Reports (May 2005); A.D. Pharma (notox -The All Natural Way to Reduce the Ill Effects of Alcohol), Report # 4163, NAD Case Reports (April 2004); Avon Products, Inc. (Skin-So-Soft Bug Guard Plus IR 3535 Insect Repellent), Report #3922, NAD Case Reports (August 2002).

[34] Bio-Foods, Inc./Balance Nutrition Bars, Report #3440, NAD Case Reports (Feb. 1998).

[35] In example 18 of the FTC's Health Products Compliance Guidance, the Commission describes a hypothetical website for a sports drink that touts a "clinically tested ingredient" for improving blood flow and increasing endurance. The FTC states, in this context, the phrase "clinically tested ingredient" implies not just that the ingredient was tested, but also that the test results prove a benefit for blood flow and endurance. *See* https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[36] Zurvita recommends only that the H20 Mix should be taken as needed to supplement hydration needs or as directed by your physician.

August 13, 2024

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