

**BBB NATIONAL PROGRAMS, INC.**  
The Direct Selling Self-Regulatory Council  
Case Number 46-2021: –Monitoring Inquiry– Root Wellness, LLC

**Company Description**

Root Wellness, LLC (“Root Wellness” or the “Company”), a direct selling company located in Brentwood, Tennessee, founded in 2019, offers health and wellness nutritional supplement products.

**Basis of Inquiry**

The Direct Selling Self-Regulatory Council (DSSRC) is a national advertising self-regulation program administered by BBB National Programs. This inquiry was commenced by DSSRC pursuant to its ongoing independent monitoring of advertising and marketing claims in the direct selling industry.

DSSRC identified the following representative product performance claims being disseminated on the Company website and by Company salesforce members on social media. DSSRC was concerned that the representative claims below communicate that Root Wellness products can protect against serious health-related conditions.

- “ROOT Testimonial Tuesday  
Fatty Liver, Psoriasis, Childhood ADHD, Chronic Fatigue”
  
- “...for over 10 years I have suffered with what is medically diagnosed as medium/aggressive Psoriasis...mainly on my legs...last year it took a severe twist...it became infected and I had Cellulitis which could have lead to possible amputation...I think you will find the photographs will outline where I was...it was a very worrying time and as I am sure you can appreciate I genuinely did not know what my future help. I was put on a course of Methotrexate and I have to say it saved the day and I started to improve. But the scars and scaly skin remained...AS most people who suffer with Psoriasis will tell you its not just the typical scarring you live with it's the Psychological scars...living in Sunny Cyprus I was not able to wear shorts and sunbathe...as people do not understand this dreadful disease...creams ointments...constant visits to Dermatologists...all with different interpretations of how to address the issue !! Expensive applications and even a trip to the dead sea in Israel...as this is supposed to offer a healing mineral...so after all these years and realizing I was actually dealing with an auto immune problem so started using Keto diets...vitamins and minerals which have helped but still the scarring remained and had to lean on steroid ointments to keep under control...so a life of steroid and methotrexate was now a reality...then I was introduced to you lovely people...Clean Slate. WOW...Following the instructions 2 x 10 drops per day for 3 weeks and I think you will see the changes. No itching, scratching...no ointments apart from moisturizing...I have stopped taking methotrexate and at last I can see light at the end of this dreadful 10 year tunnel...”

- Images of psoriasis healing over 8 weeks time
- “Our Autism Journey - Non-verbal no longer! Hi! My son Michael turned 14 in January 2021. He had been completely non verbal since he was about 15 months old. Stephanie reached out to me and invited me to a zoom call, to discuss a heavy metals detox product (Clean Slate). I was impressed by everything I heard on the call, so I gave it a try. Within 10 days my son was sleeping through the night (something he had never done). He was taking naps during the day too, on some days. By the end of the 3rd week, he started mumbling consonants : the first ones I noticed were g, b and m. With some practice, he could say his name, (Michael), Koko, come, go, about half of the letters of the alphabet. With colours, numbers and letters of the alphabet, it was obvious that he had been learning things all these years, but just couldn't express himself. We are about 3 months in with Clean Slate now, his skin is clear (he had some recurring patches), he is calm and confident and is gaining new words. We are so happy about the progress he is making and sooooo excited for the future!!!”
- “Once you’re on your Maximum then you’re going to notice it And then you will see the results in the blood results too... Fibromyalgia Rheuma Arthritis Psoriasis Eczema Darmon Disorders and Still a lot more can be treated with it”
- “My favorite ‘side effects’ of this product: Morning fog has been lifted, Belly bloat has been blasted, AND long time stubborn nail fungus? Dissolving, as if by magic! These two products truly support the quest for an EMPOWERED lifestyle!!! – Olenka C.” <https://therootbrands.com/reviews>
- “My 79 year old husband was showing signs of dementia and had given up playing the trumpet, his difficulty in speaking clearly and finding the right words had become more pronounced. He started both products in March and is back to daily trumpet practice. His speech is slowly improving and while he still has difficulties, he is holding longer conversations. He had avoided speaking except to family and close friends so this is a great sign. Also, he is back to his Painting and his Astrological pursuits. I take both products and tell my friends 82 is the new 62 but truly feel my energy and focus is like being back in my fifties. – Joy H. <https://therootbrands.com/reviews>
- “I was introduced to Clean Slate several months ago and I am noticing some of my autoimmune symptoms are subsiding, my skin is amazing and those pesky sugar cravings are gone. I am pleasantly surprised and can’t wait to see what happens in another 3 months!” <https://therootbrands.com/reviews>

### **Company’s Position**

According to the Company website, Root Wellness offers three products:

- a) Clean Slate: Clean Slate is a zeolite-based proprietary patent-pending formulation that supports the removal of toxins from cells, body, and brain tissue. According to the Company, Clean Slate assists in the reduction of negative inflammation and supports the absorption of nutrients by the removal of toxins which may block nutrient binding.
- b) Zero-In: Made with turmeric, pine bark, velvet bean seed, and vitamin D, Zero-In helps support increased attention span and concentration levels through a natural, proprietary brain formula and aids healthy brain function and focus while improving the delivery of oxygen to cells.
- c) Restore: Restore is described on the Company website as a weight-loss aid that contains “everything your body needs to run full of energy all day long.” The product also purportedly provides antioxidant and anti-inflammatory benefits and supports bone health, healthy blood pressure, and the immune system.

#### Published Articles and Studies on Product Ingredients

The Company provided several published articles to DSSRC, which it maintained demonstrated a direct correlation between the ingredients contained in Root Wellness products with the improvement of certain health-related conditions. A summary of the documentation provided by Root Wellness is provided below:

In an article entitled Biological and therapeutic effects of ortho-silicic acid and some ortho-silicic acid-releasing compounds: New perspectives for therapy,<sup>1</sup> the authors concluded that ortho-silicic acid might be a prominent therapeutic agent in humans. Some potential therapeutic and biological effects on bone formation and bone density, Alzheimer disease, immunodeficiency, skin, hair, and nail condition, as well as on tumor growth. The article noted that the most important sources that release ortho-silicic acid as a bioavailable form of silicon are colloidal silicic acid, silica gel, and zeolites.

The article explained that although all these compounds are characterized by substantial water insolubility, they release small, but significant, equilibrium concentration of ortho-silicic acid in contact with water and physiological fluids. Even though certain pharmacological effects of these compounds might be attributed to specific structural characteristics that result in profound adsorption and absorption properties, the compounds all exhibited similar pharmacological profiles readily comparable to ortho-silicic acid effects. The authors stated that the most unusual ortho-silicic acid-releasing agents are certain types of zeolites and that numerous biological

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<sup>1</sup> Jurkić, L.M., Capanec, I., Pavelić, S.K. *et al.* Biological and therapeutic effects of ortho-silicic acid and some ortho-silicic acid-releasing compounds: New perspectives for therapy. *Nutr Metab (Lond)* 10, 2 (2013).

activities of some types of zeolites documented might be attributable to the ortho-silicic acid-releasing property.

In conclusion, the article determined that the therapeutic perspectives of both ortho-silicic acid and ortho-silicic acid -releasing derivatives provide additional insights into biological mechanisms of action and require larger studies on both animals and humans.

A 2003 study provided by the Company entitled Anticancer And Antioxidative Effects Of Micronized Zeolite Clinoptilolite<sup>2</sup> evaluated micronized zeolite on various tumor cell cultures and tumor bearing animals. Root Wellness maintained that according to the results of the study, dosages of between 0.05-0.5 mg/ml of micronized zeolite led to the improvement of the overall health status, prolongation of life and a decrease of tumor size in some cases. The test administrators concluded that the data confirmed that malignant and normal cells respond differently to the antioxidant effects of micronized zeolite, which means that micronized zeolite could have antioxidative and anti-tumor effects at the same time.

Another study submitted by the Company, Antiviral Properties Of Clinoptilolite,<sup>3</sup> concluded that concentrations of 0.5 and 5mg/ml of micronized zeolite induced a very low antiviral effect or the antiviral was not observed at all, while, conversely, concentrations of 12, 25, and 50mg/ml of micronized zeolite induced a significant inhibitory effect upon viral proliferation. The preliminary results of the study indicated an antiviral property of clinoptilolite at higher concentrations that open a possibility of therapeutical application of micronized zeolite either locally (skin) against herpes virus infections or orally in cases of adenovirus or enterovirus infections.

Root Wellness also maintained that its submission of a published article, "A Critical Review On Zeolite Clinoptilolite Safety And Medical Applications In Vivo"<sup>4</sup> supported the health effects and safety in medical applications of different clinoptilolite-based materials. The authors concluded that clinoptilolite-based materials may be regarded as safe for in-vivo consumption. A variety of highly positive effects on human animal health were documented for clinoptilolite based materials. The study noted that due to clinoptilolite's ion exchange and adsorption properties and consequent detoxifying effects it is proven useful for the elimination of a variety of contaminants from the body.

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<sup>2</sup> Zarkovic N, Zarkovic K, Kralj M, Borovic S, Sabolovic S, Blazi MP, Cipak A, Pavelic K. Anticancer and antioxidative effects of micronized zeolite clinoptilolite. *Anticancer Res.* 2003 Mar-Apr;23(2B):1589-95. PMID: 12820427.

<sup>3</sup> Grce, Magdalena & Pavelić, Krešimir. (2005). Antiviral properties of clinoptilolite. *Microporous and Mesoporous Materials - MICROPOROUS MESOPOROUS MAT.* 79. 165-169. 10.1016/j.micromeso.2004.10.039.

<sup>4</sup> Kraljević Pavelić S, Simović Medica J, Gumbarević D, Filošević A, Pržulj N, Pavelić K. Critical Review on Zeolite Clinoptilolite Safety and Medical Applications *in vivo*. *Front Pharmacol.* 2018;9:1350. Published 2018 Nov 27. doi:10.3389/fphar.2018.01350

In "Neuroprotective Actions of Clinoptilolite and Ethylenediaminetetraacetic Acid Against Lead-induced Toxicity in Mice *Mus musculus*,"<sup>5</sup> the study administrators investigated the occurrence of oxidative stress in developing animals due to lead (Pb(2+))<sup>6</sup> neurotoxicity in the brain regions of mice. Root Wellness maintained that the results of study indicated the neuroprotective potential of clinoptilolite and ethylenediaminetetraacetic acid against Pb(2+) toxicity.

In another study<sup>7</sup> on mice provided by Root Wellness, surface chemistries were evaluated for heavy metal capture from biological fluids, various facets of the materials' biocompatibility, and the suitability of these materials as potential therapeutics. Of the materials tested, thiol-functionalized self-assembled monolayers on mesoporous supports (SAMMS) proved most capable of removing selected heavy metals from biological solutions (i.e., blood, urine, etc.). Consequentially, thiol-functionalized SAMMS was further analyzed to assess the material's performance under a number of different biologically relevant conditions (i.e., variable pH and ionic strength) to gauge any potentially negative effects resulting from interaction with the sorbent, such as cellular toxicity or the removal of essential minerals. Additionally, cellular uptake studies demonstrated no cell membrane permeation by the silica-based materials generally highlighting their ability to remain cellularly inert and thus non-toxic. As a result, the authors concluded that organic ligand-functionalized nano porous silica materials could be valuable for detoxification therapeutics and potentially other biomedical applications as needed.

The Company maintained that the bioavailability of silicon was supported by a published review entitled "Biological and therapeutic effects of ortho-silicic acid and some ortho-silicic Acid-releasing compounds: New perspectives for therapy."<sup>8</sup> According to the article, zeolite is among the most important sources that release ortho-silicic acid as a bioavailable form of silicon and that the most unusual ortho-silicic acid-releasing agents are certain types of zeolites, a class of aluminosilicates with well described ion(cation)-exchange properties.

As further support for its position that clinoptilolite treatment might affect cancer growth, Root Wellness provided DSSRC with an evaluation of clinoptilolite treatment of mice and dogs suffering from a variety of tumor types, which led to improvement in the

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<sup>5</sup> Basha MP, Begum S, Mir BA. Neuroprotective Actions of Clinoptilolite and Ethylenediaminetetraacetic Acid Against Lead-induced Toxicity in Mice *Mus musculus*. *Toxicology International*. 2013 Sep;20(3):201-207. DOI: 10.4103/0971-6580.121666.

<sup>6</sup> Pb+2 is the more oxidative state of lead, the densest of the common metals excepting gold and mercury. It has a metallic luster when freshly cut but quickly acquires a dull color when exposed to moist air.

<sup>7</sup> Yantasee W., R.D. Rutledge, W. Chouyok, V. Sukwarotwat, G. Orr, C.L. Warner, and M.G. Warner, et al. 2010. "Functionalized Nanoporous Silica for Removal of Heavy Metals from Biological Systems; Adsorption and Application." *ACS Applied Materials & Interfaces* 2, no. 10:2749-2758. PNNL-SA-73483. doi:10.1021/am100616b

<sup>8</sup> Jurkić LM, Ceganec I, Pavelić SK, Pavelić K. Biological and therapeutic effects of ortho-silicic acid and some ortho-silicic acid-releasing compounds: New perspectives for therapy. *Nutr Metab (Lond)*. 2013 Jan 8;10(1):2. doi: 10.1186/1743-7075-10-2. PMID: 23298332; PMCID: PMC3546016.

overall health status, prolongation of lifespan, and decrease in tumor size.<sup>9</sup> In this study, local application of clinoptilolite to skin cancers of dogs effectively reduced tumor formation and growth. In addition, toxicology studies on mice and rats demonstrated that the treatment did not have negative effects.

### Heavy Metal Testing

Root Wellness provided DSSRC with the results from seven individuals who used a 24-hour home urine test kit to screen or detect for the presence of 22 different heavy metals in the body. The tests were conducted between September 2018 and May 2020. The results indicated that presence of several heavy metals decreased after using the test product.

### Heart Rate Variability Study

The Company provided DSSRC with a single case study evaluating the effects of the Company's Clean Slate and Zero-In on the regulation of the body using a Nilas-MV heart rate variability monitoring system. The study measured the influence on vegetative nervous system and stress index; the balancing of the processes in the body - in particular, the neurotransmitter systems; the improvement of the sleep cycle; and the promotion of a longer and healthier life and influences on metabolism. Root Wellness maintained that the study supported its position that its two products lead to less tension, improved cardiovascular function, better brain function, a better overall feeling, an improvement of the psycho-emotional condition and to a more restful sleep.

The study was conducted by clipping two electrodes near the subject's wrist and a 5-minute measurement to get 300 heartbeat intervals. After the initial test, the subject was administered 10 drops of the Clean Slate product and two caps of Zero-One. After the initial baseline measurement, a heart rate variability test was performed 45 minutes after ingestion. To see how long the effect of Root Wellness' Clean Slate and Zero-In products are effective in the body, further measurements were then taken. According to Root Wellness, after administration of the products, the results showed a healthy heart rate variability index and all physiological systems increased by more than 50% after 45 minutes.

### ROFES Study

The ROFES method is based on a measurement of the biological point on the inside of the left wrist bypassing an electrical microcurrent pulse through all organs. The device is attached to the left hand in such a way that the active electrode of the device rests on the biologically active point on the left wrist. The computer program then

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<sup>9</sup> Pavelić K, Hadzija M, Bedrica L, Pavelić J, Dikić I, Katić M, Kralj M, Bosnar MH, Kapitanović S, Poljak-Blazi M, Krizanac S, Stojković R, Jurin M, Subotić B, Colić M. Natural zeolite clinoptilolite: new adjuvant in anticancer therapy. *J Mol Med (Berl)*. 2001;78(12):708-20. doi: 10.1007/s001090000176. PMID: 11434724.

compares the measured values received with the normal values corresponding to the organism of a healthy person according to his age.

The ROFES tests the functional state of 17 important organs and systems and shows how stress, physical strain, wrong nutrition, harmful habits, weather changes, environmental problems, etc., affect the body. According to Root Wellness, the test is a reliable indicator of how each individual organ reacts to and adapts to these stresses and that the test data indicated a significant decrease in the markers meaning that the test subject had a high level of health and energy resource after being administered the Company's Clean Slate and Zero-In products.

### **Case Disposition**

Root Wellness engaged with DSSRC at the beginning of the self-regulatory inquiry by participating in telephone calls and providing DSSRC with studies, which it contended supported the claims at issue. However, the Company failed to respond to DSSRC's follow-up correspondence requesting additional information about the materials that were originally provided by the Company. Notwithstanding, during the pendency of the inquiry, it appeared that Root Wellness removed the review page on the Company website from which three of the testimonial claims at issue appeared (i.e., <https://therootbrands.com/reviews>).<sup>10</sup> DSSRC determined that the apparent removal of the review page from the Company website was necessary and appropriate and, accordingly, the continuing basis for the self-regulatory inquiry was limited to the remaining social media posts.

DSSRC determined that the social media posts at issue include claims that Root Wellness products can treat a number of serious health related conditions including, but not limited to, psoriasis, attention-deficit/hyperactivity disorder, chronic fatigue, fatty liver disease (Hepatic Steatosis), fibromyalgia, and rheumatoid arthritis.

DSSRC disagreed with Root Wellness' contention that because the Company did not authorize the claims disseminated in the social media posts it was not responsible for the representations made by its independent salesforce members (i.e., Root Ambassadors). As DSSRC has noted in past inquiries, for purposes of a self-regulatory inquiry, the fact that a social media post from a direct selling company's independent salesforce members was not authorized by the company does not absolve the company from any responsibility regarding the post.<sup>11</sup> DSSRC received no

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<sup>10</sup> Although the Root Wellness review page is no longer publicly accessible, the link now takes users to a log-in page. DSSRC was unable to ascertain if logging in to the page would take users to the reviews containing the testimonial claims that were the subject of the DSSRC inquiry. Should those consumer reviews continue to be disseminated behind a log-in wall, DSSRC recommended that the Company take the appropriate action to have those reviews disabled, as they reference a number of health-related benefits from using Root Wellness products that have not been supported by competent and reliable scientific evidence.

<sup>11</sup> Pursuant to Section (I)(D) of the DSSRC Policy & Procedures, a company shall voluntarily not raise the independent contractor status of salespersons distributing their products or services under its trademark or trade name as a defense against non-compliance with DSSRC standards, provided, however, that such

indication from Root Wellness that it made any effort to contact the independent salesforce members who disseminated the posts or took any enforcement measures to reconcile the matter. As noted in his October 15, 2020, remarks to the Direct Selling Association, FTC Commissioner Noah Philips stated that “claims made by salesforce members are attributable to direct selling companies themselves.”

As to the health-related claims at issue, it is well established that health-related claims should be supported by competent and reliable scientific evidence.<sup>12</sup> The FTC generally defines competent and reliable scientific evidence as: “test, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”<sup>13</sup>

While the Company provided a number of studies which it maintained demonstrated that some individual ingredients contained in Root Wellness’ Clean Slate and Zero-In products could be beneficial at removing certain heavy metals and toxins from the body, DSSRC concluded that the studies did not provide the necessary evidence to show that using the Company’s products as directed would result in relieving or diminishing the specific health-related conditions<sup>14</sup> referenced in the social media posts at issue. For example, a number of studies provided by Root Wellness did not indicate that the resulting data was statistically significant and there was no confirmation that dosages of the ingredients evaluated in the studies correlated with the presence of the ingredient as found in the Root Wellness products. More specifically, even had DSSRC determined (which it did not) that the studies provided by Root Wellness met the competent and reliable scientific evidentiary threshold that is necessary for health-related claims, it would nevertheless be inappropriate to extrapolate the resulting test data that, for example, reported diminished toxin levels in individual urine samples to mean that product can be beneficial to people suffering from health conditions such as psoriasis, attention-deficit/hyperactivity disorder, chronic fatigue, fatty liver disease (Hepatic Steatosis), fibromyalgia, and rheumatoid arthritis.

When a direct selling company and/or its salesforce members disseminate claims that its product is effective at protecting consumers from specific health-related conditions, it is imperative that the company provide reliable and competent testing indicating that the products are efficacious against those stated conditions.

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action shall not be construed to be a waiver of a company’s right to raise such defense under any other circumstance.

<sup>12</sup> VGH Solutions Inc. (*Dr. Ho’s Circulation Promoter* ), Report #6404, *NAD/CARU Case Reports* (September 2020); Molekule Inc. (*Molekule MH1 Air Purifier*), Report #6314, *NAD/CARU Case Reports* (October 2019); Triumph Pharmaceuticals Inc. (*SmartMouth Dry Mouth Products*), Report #6190, *NAD/CARU Case Reports* (June 2018); Good Health Naturally, LLC (*Serranol Supplements*), Report # 5441, *NAD/CARU Case Reports* (March 2012); Nature’s Cure, Inc. (*2 -Part Acne Treatment*), Report #4797, *NAD/CARU Case Reports* (February 2008).

<sup>13</sup> FTC Guide, *Dietary Supplements: An Advertising Guide for Industry*, [www.business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry](http://www.business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry);



Moreover, Root Wellness did not respond to DSSRC's request for additional information regarding its testing data, including questions about the statistical significance of the resulting data, the use of animals in the individual ingredient studies, and the small sample sizes and testing methodology used in the heavy metal, heart rate variability, and ROFES studies.

As such, in the absence of reliable and competent evidence indicating that the products perform as claimed, DSSRC recommended that the Company take immediate action to have the remaining social media posts containing the health-related claims at issue in this inquiry disabled.

### **Conclusion**

During the pendency of the inquiry, it appeared that Root Wellness removed the review page on the Company website from which three of the testimonial claims at issue appeared. DSSRC determined that the removal of such review posts was necessary and appropriate. In addition, DSSRC also concluded that the evidence provided by Root Wellness was not of sufficient reliability to support the remaining claims that were disseminated on social media by Company salesforce members that its products can protect consumers against the specific health related conditions communicated in the posts. Accordingly, DSSRC determined that Root Wellness should take immediate action to disable those posts at issue which remain publicly accessible by consumers

### **Company Statement**

"We at ROOT are diligently working to track clinical outcomes with scientific data to support the ROOT brand products. We recognize consumer claims can create perception issues which lead to regulatory compliance concerns and this isn't the image our company and brand portray as we understand the compliance landscape. We have taken the review page down from our website as an immediate move to assure we are focusing on a proper consumer facing approach to claim compliance. In addition, we are working with our community members who have made their personal experience claims on social media to correct any improper claims found on third party sites."

(Case No. 46-2021 PCM, closed on 09/16/21)  
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