

BBB NATIONAL PROGRAMS, INC.
The Direct Selling Self-Regulatory Council

Case Number: 22-2020– Competitor Challenge

INQUIRY BACKGROUND

Founded in 2018, BioReigns (or the “Company”) is a multi-level direct selling company that markets cannabidiol (CBD) associated health supplements. Certain marketing claims for BioReigns were challenged by MyDailyChoice, Inc. (or the “Challenger”) a multi-level direct selling company that offers a variety of products, including a portfolio of products containing CBD.

BASIS OF INQUIRY

The Direct Selling Self-Regulatory Council (DSSRC), is a national advertising self-regulation program administered by BBB National Programs, Inc. This inquiry was commenced by MyDailyChoice pursuant to the competitor challenge provisions articulated in section D (III) of the DSSRC Policies & Procedures.

More specifically, MyDailyChoice initiated this challenge regarding earnings claims and product performance claims that it alleged were being inappropriately disseminated on the Company’s website and on social media posts by BioReigns’ distributors.

The representative claims and issues that were the subject of this review are as follows:

A. Health-Related Product Performance Claims

- Claims that the Company’s products treat “pain,” “anxiety,” “depression,” “limiting cancer cell growth,” “epileptic seizures,” “Alzheimer’s disease,” “migraines and headaches.”
- “Perfect health solution,” “maximum bioavailability,” “proven with real people,” “eating and living well is not enough,” “increased mental clarity,” “less aches,” “joint support,” “immune support,” “weight management,” “more energy.”
- “100% availability,” “proven power of water-soluble CBD,” “anti-inflammatory,” “decreased inflammation,” “increased brain function,” “enhanced mental balance,” “improve sleep,” “improve cell health,” “stamina,” “mood enhancement,” “endurance,” “improve physical performance,” “increase body’s natural metabolic responses,” “more calories and fat being burned in support of weight loss goals,” “deeper sleep,” “muscle and joint relief,” “pain relieving salve,” “may relieve everyday aches and pains,” “pain relieving benefits of CBD,” “formula aids in skin cell regeneration not only on the face, but anywhere on the body.”

- CBD lean –“burn fat at a higher rate and maximizes results,” “more effectively burn through all of your carbs and proteins which will then allow your body to burn fat’,” “once you are in this state, you will have perfect energy, perfect focus and perfect fat loss,” “you will feel a difference with BioReigns products, you will see the results, you will accomplish what everyone wants in life. A happier, healthier you.”
- “BioReigns CBD Daily BroadSpectrum Tincture is an all-natural, and oil-free product that contains our BioCx - Water Dissolvable CBD Complex with curcumin complex. This tincture is a clean, pure and water dissolvable product, making it more bioavailable than any CBD oil product on the market.”
- “BioReigns CBD Daily Full Spectrum Tincture is an all-natural, and oil-free product that contains our BioCx with CBD and curcumin complex. This tincture is a clean, pure and water dissolvable product, making it more bioavailable than any CBD oil product on the market. With our innovative water dissolvable technology, the active ingredients included in our Full Spectrum Complex, enter your system quickly so you can enjoy the Entourage Effect.”



BioReigns BioDefense

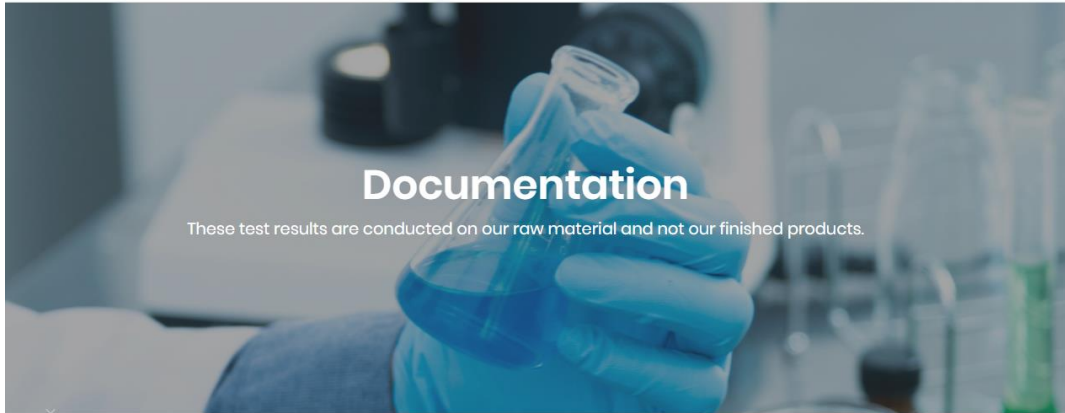
3 months ago | More



- “Start your day with our energy-inducing, all-natural Limitless capsules, with Brain-Derived Neurotrophic Factor (BDNF) peptides. Some have even replaced their pre-workout supplement with our Limitless capsules. Brain-Derived Neurotrophic

Factor (BDNF) is active in the hippocampus, cortex and basal forebrain areas of our brain and its vital to learning, memory and higher-level thinking.”

- “Maximize your body’s natural ability to burn calories. CBD Lean may give you the boost you need to burn fat and lose weight without high levels of caffeine and other stimulants. CBD Lean also works amazing when used in conjunction with Limitless and other BioReigns products.”
- “Experience our mild and soothing, non-greasy cream. BioReigns RELIEF Cream is infused with our proprietary blend of BioCxWater Dissolvable CBD Complex, menthol, camphor and arnica. This formulation provides a rapid cooling effect to help your body after a hard day. The BioReigns RELIEF Cream is packaged in a convenient and portable lotion dispenser, that is well suited for applications in both large and small areas of the body. The dispenser pump is designed to prevent excessive exposure to the air while making it easy to get the most out of the cream without the unnecessary wasting of product.”
- “Roll on the RELIEF. All the benefits of the BioReigns RELIEF Cream now available in an easy roll on! With an easy pop of the cap, our proprietary blend of Water Dissolvable BioCX – CBD Complex, menthol, camphor, and arnica is rolled directly on to the desired area. Perfect for the athlete on the go or easy to use at home! Roll on into Relief with BioReigns.”
- “Our sought-after RELIEF salve combines BioReigns proprietary, Water Dissolvable BioCx – CBD complex, infused with menthol, camphor and peppermint oil. This powerful balm is applied directly to the desired area. BioReigns RELIEF Salve contains only organic and sustainably sourced ingredients.”
- The Challenger alleged that BioReigns also inappropriately presents independent test results as “BioReigns Documentation and Scientific Information.”
- The Challenger alleged that three certificates of analysis (COAs) that are posted on the BioReigns website for its isolate, broad spectrum and full spectrum ingredients improperly communicate the purity and presence of the CBD ingredient in BioReigns products.



These test results are conducted on our raw material and not our finished products.

BROAD SPECTRUM

View

ISOLATE

View

FULL SPECTRUM

View

- The Challenger alleged that the test report posted on the BioReigns website is insufficient to support its claim that its products are “passing the blood-brain barrier” and have an actual physiological effect on the brain.

In addition to the claims listed above, MyDailyChoice called DSSRC’s attention to several other links to claims disseminated by BioReigns and/or its salesforce which the Challenger maintained included unsupported product performance claims.¹

¹ <https://player.vimeo.com/video/324841970>;
<https://vimeo.com/319594496>;
<https://vimeo.com/375309513>;
<https://vimeo.com/375310545>;

B. Earnings Claims

- “Binary Commissions are going to be what sustains your business over the long term. This is how you will build LONG-TERM residual income. BioReigns has put together the most lucrative Binary pay structure in the industry. By paying out as much as 20% on your weaker leg volume, you are able to take advantage of being paid through an INFINITE amount of levels.”
- “It is important to note that the Personal Qualifying Commission (PQV) is from your Personal Monthly order.”
- “Autoship—This is your monthly PQV order that you automatically set up for shipment in your back office. This is a Rank Requirement.”
- “Personal Qualifying Volume (PQV) – This is the monthly volume you personally need in order to stay Rank Qualified.”
- “You can live the life of your dreams, be your own boss, help others get healthier while you build residual income with our profitable and aggressive Distributor’s Compensation Plan and our innovative product line. Take your business to the next level like never before with our Rank Bonuses and the Elite Expense Accounts.”
- "Help your three friends sell three elite packs to three new distributors to receive your rank advancement to Elite 5k"

CHALLENGER’S POSITION

A. Product Performance Claims

MyDailyChoice contended that BioReigns has premised its entire marketing strategy on false and unsubstantiated health-related and disease treatment claims. The Challenger alleged that BioReigns failed to satisfy its burden to provide competent and reliable scientific evidence to support its health-related claims. The Challenger further

<https://vimeo.com/3755S5022>; <https://vimeo.com/386377623>
<https://www.facebook.com/groups/TheBioreignsExperience/>
<https://vimeo.com/379156973>;
<https://www.facebook.com/sumxoxos/videos/10157248105307872/?notifid=1580956218405166¬ifit=live> video explicit; <https://tools.bvdesign.com/Bioreigns/Share/Featured/NQ==/Mzc00TA=>;
<https://bioreigns.com/about-bioreigns/documentation>;
<https://bioreigns.com/products> <https://www.facebook.com/iojocontino> BioReigns Founder JOJO Dominic Contino; <https://www.facebook.com/groups/TheBioreignsExperience/>
<https://www.youtube.com/watch?v=QzD7RqTrrJA>

maintained that BioReigns began making some of its most egregious claims after the self-regulatory inquiry was commenced.

For example, MyDailyChoice pointed to several posts and videos which it maintained included several disease claims including an image of the heart and an image of an electrocardiogram (EKG) report which it maintained communicated an implied heart health claim. The Challenger stated that according to the FDA Small Entity Compliance Guide on Structure Function Claims “Some symbols, like the heart symbol, are so widely recognized as symbols for disease treatment and prevention that their use is ordinarily an implied disease claim.”²

The Challenger asserted that BioReigns salesforce members have also expressly claimed that its products help treat or prevent, among other things, cancer, Alzheimer’s, COVID-19, neuro-inflammation, depression, epileptic seizures, anxiety, migraines, pain, and sleeplessness.

MyDailyChoice pointed to BioReigns claims for its BioDefense product as an example. Specifically, the Challenger called DSSRC’s attention to a March 16 video titled, “BioReigns Corporate Update,” in which BioReigns’ Founder and CEO discussed the serious health risks at issue, school closures, event cancellation, and the ability to “take advantage” of working from home with BioReigns and then introduces BioReigns’ new product, BioDefense. The Challenger noted that the video included the following language:

“We have taken it upon ourselves to utilize R&D and come up with something that we feel can benefit you and everyone around you. ... BioReigns would like to introduce to you BioDefense. ... I’ve read multiple studies that show these supplements have the bioavailability to stimulate the immune system and make certain types of immune cells better at destroying germs.”³

The Challenger contended that, although the pandemic is not expressly mentioned in the video, by showing images of viruses resembling COVID-19 and claiming that it pivoted quickly in response to present circumstances to develop an immunity based “solution” utilizing R&D, the context for BioReigns’ product release was clearly the current health crisis.⁴ MyDailyChoice asserted that BioReigns has no basis for making any product claims pertaining to COVID-19.⁵

² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>

³ <https://vimeo.com/396632161/e1edd0eadd> (published March 16, 2020) (3:00–6:15, BioDefense product to be released that Wednesday (3/19) for sale).

⁴ The challenger noted that BioReigns released the video and similar marketing materials in mid-March with a product release date of March 19, shortly after President Trump declared a national emergency on March 13.

⁵ MyDailyChoice noted that BioReigns has published other marketing material promoting its “BioDefense product,” product, “Formulated To Boost The Immune System” in the context of the pandemic.

The Challenger referred to statements from various regulatory agencies as support for its position that depending on how it is phrased, or the context in which it is presented, a statement about a product's effect on a normal 'structure or function' of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. The Challenger maintained that if elements of the advertisement imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the advertisement contains no express reference to disease.⁶

MyDailyChoice also disputed the consumer relevancy and conspicuousness of the disclaimer that appears in marketing materials for BioReigns' BioDefense product. ("Any claims that BioReigns products cure, treat, diagnose, mitigate, or prevent any medical condition or disease, including COVID-19, violate our corporate policies and federal law.") The Challenger argued that the disclosure is particularly problematic given deep-linking and the use of direct citations to product pages and videos rather than the homepage. MyDailyChoice asserted that advertisers cannot deliberately convey one message and then purport to cure their deception with a disclaimer and, similarly, cannot, "use fine print to contradict other statements in an ad or to clear up misimpressions that the ad would leave otherwise."⁷ Accordingly, the Challenger argued that BioReigns cannot rely on the fine-print on its homepage to justify its overt efforts to induce consumers to purchase "extra-strength" and "ultra-strength" BioDefense as a "solution" in helping to protect against COVID-19.

Depiction of Test Results on BioReigns website

The Challenger noted that BioReigns posts three Certificates of Analysis (COAs) on its website: isolate, broad spectrum, and full spectrum to support claims about its products' purity, which the Challenger argued communicate an inaccurate message to consumers. More specifically, MyDailyChoice argued that the test results displayed by BioReigns on its website are of the raw feed stock presumably used to produce the product and not the finished product itself.⁸

Specifically, the Challenger contended that BioReigns continues to engage in deceptive practices by pointing to COAs for its raw materials on its "Documentation" page and did so despite BioReigns' concession that the COAs do not have anything to do with

See e.g. <https://vimeo.com/398432129> (published March 18, 2020). After noting the importance of frequently washing your hands and not touching your face, the video states that "for people wanting to do more than this, BioReigns can offer them BioDefense." (0:21-42).

⁶ See <https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirusdisease-2019-covid-19-products> and <https://www.fda.gov/inspections-complianceenforcement-and-criminal-investigations/warning-letters/santiste-labs-llc-607227-04272020> (Warning Letter from FDA and the Federal Trade Commission to seller of "Defend Patch" based on claims that in response to the pandemic it created a product that can boost the immune system using proprietary technology).

⁷ <https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business>

⁸ According to MyDailyChoice, on the Full Spectrum Certificate of Analysis,, A⁹-THC is omitted. Total THC is calculated as if A⁹-THC is omitted (0.87* T HCA) + A⁹-THC = Total THC.

its finished products. As such, MyDailyChoice maintained BioReigns has justified its refusal to provide actual product COAs based on the position that there is no legal requirement to do so while simultaneously publishing other misleading COAs.

In addition, the Challenger provided DSSRC with independent third-party testing conducted to evaluate actual CBD purity levels in three BioReigns products: CBD Daily Full Spectrum, BioReigns Limitless and BioReigns Pet Tincture. According to MyDailyChoice, the results showed no detectable CBD in the corresponding BioReigns products. Accordingly, the Challenger argued that BioReigns' decision to post test results of its raw feed stock instead of test results for actual final product was an effort by the Company to obscure the fact that many of the BioReigns' CBD products don't actually contain any detectable CBD.

MyDailyChoice also asserted that BioReigns coordinated the testing process in furtherance of its product claims and therefore the Company's testing could not be considered "independent." The Challenger further maintained that actual, independent third-party test results contradict the Company's implied claims and maintained that BioReigns' position that it worked with Advanced Botanical Consulting and Testing Inc. (ABC) to develop an entirely new testing protocol was in violation of U.S. Food and Drug Administration ("FDA") testing standards.

The Challenger provided DSSRC with copies of warning letters from the FDA that were sent to ABC based on significant analytical testing violations at its facility, most recently in June 2019. According to the Challenger, ABC's violations were particularly concerning to the FDA because ABC issued a COA stating that a particular bacteria was not detected in one of the drugs at issue, but the FDA had tested the same lot, found the bacteria to be present, and noted that at least 60 confirmed cases of illness or death were associated with the presence of the bacteria in the product.⁹

According to MyDailyChoice, the FDA found that ABC (1) failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of its test methods, and failed to determine whether its testing methods were appropriate; (2) failed to ensure its records included complete data; (3) failed to exercise appropriate controls over its records to ensure the integrity of its results; and (4) failed to routinely calibrate, inspect, and check its equipment, with many pieces of equipment out-of-calibration. The FDA emphasized the fact that ABC failed prior inspections dating back to 2012. As a result, the Challenger maintained that FDA concluded ABC engaged in repeat violations, defied prior FDA directives, and demonstrated a lack of executive management and oversight.¹⁰

⁹ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/advanced-botanical-consulting-testing-inc-dba-abc-testing-572991-06042019>

¹⁰ Additionally, the challenger stated that the FDA Warning Letters also present significant concerns as to ABC's testing of dietary supplements. For example, MyDailyChoice noted that the Trust Transparency Center reviewed the FDA letters and explained these concerns in detail. The challenger called DSSRC's attention to the FDA's statement that: "It should be noted and perhaps emphasized that while ABC's current

As further corroboration of its position that BioReigns is providing inaccurate information regarding the CBD content in its final product, MyDailyChoice referred DSSRC to an investigation to be conducted by Inside Edition, an American television program, that identified a de minimis amount of CBD in BioReigns products. According to the Challenger, the broadcast stated, in relevant part, that:

"We also had a lab test a CBD product sold by Slade Smiley and Gretchen Rossi of "The Real Housewives of Orange County." The label on the product stated it had 560 mg of CBD and curcumin, an herbal supplement. But the lab tests showed the product only had about 1 mg of CBD."

The Challenger stated that it is well established that consumers should never purchase CBD products from companies that refuse to provide COAs on the actual products that are sold.¹¹

Moreover, MyDailyChoice maintained that the use of a disclaimer cannot cure BioReigns' calculated efforts to deceive affiliates and consumers and asserted that the Federal Trade Commission (FTC) has made clear that advertisers cannot deliberately convey one message and then purport to "cure" their deception with a disclaimer and referenced the Commission's position that, "If a disclosure provides information that contradicts a material claim, the disclosure will not be sufficient to prevent the ad from being deceptive. In that situation, the claim itself must be modified."¹² The Challenger added that immediately following claims regarding the purported efficacy and bioavailability of its products, BioReigns prominently states "View Test Results" and argued that many affiliates and consumers will either overlook the disclaimer or will not scrutinize or appreciate the distinction between ingredient COAs and finished product COAs.

BioReigns' Quantitative Electroencephalography (qEEG) Study

The Challenger disputed the Company's use of qEEG study results to support its claim that ingredients in the BioReigns' products cross the blood-brain barrier. According to MyDailyChoice, the raw data and the description of the qEEG test protocol are lacking

violation stems from its work outside of the dietary supplements industry, the fact that the majority of their operations lie within it should create a cringe factor and relevance all the same" and that "... this Warning Letter should not be interpreted by this industry as 'merely' a drug warning; it is highly relatable to dietary supplements."

¹¹ See <https://www.consumerreports.org/cbd/how-to-shop-for-cbd/> ("If an online manufacturer or a retail store doesn't have the [COA], or refuses to share it, avoid the product and the retailer.") and <https://ecohealthsource.com/buy-cbd-certificate-of-analysis/> ("If a source won't provide the results, or says a Certificate of Analysis has not been completed, you may want to think twice about using that product for your health and wellness.")

¹² <https://www.ftc.gov/system/files/documents/plain-language/bus41-dot-com-disclosures-information-about-online-advertising.pdf>, p.5

in basic, fundamental experimental design concepts and that these flaws prove fatal to the conclusions and the related product claims that BioReigns makes from the study.

MyDailyChoice also disputed the reliability and applicability of the BioReigns qEEG study, noting that the study states that there were no significant changes after administration of both the CBD oil and nano products that were used in the test. More specifically, the Challenger noted that although CBD has been shown to reduce seizure frequency and modify EEG abnormalities in certain pathologies, there is no data that would support CBD having the observed effects in the study.

MyDailyChoice called DSSRC's attention to an absence of a negative control or placebo group in the study and that the test subjects did not appear to be properly screened for health issues, cannabis use, or bias toward the products tested which further limits the reliability of the experimental observations. According to the Challenger, placebo or negative control groups are a basic scientific principle that are used to eliminate the possibility that any observed changes in the test data is due to placebo effects and that any well-designed human study will include placebo or negative control groups, especially those relying on brain activity for observational data. The Challenger maintained that the absence of a control group to compare the observed changes in any of the treatment groups (oil, nano, or Bioreigns) prevents any supportable conclusion based upon the experimental data due to the fact that placebo effects cannot be excluded and that the potential placebo effects include both reduction in the observed Z-score, elevation in Z-score, and no change in Z-score.¹³

MyDailyChoice also asserted that the qEEG study did not include any testing observations of the effects of the BioCx carbohydrate carrier molecule without curcumin or CBD. According to the Challenger, certain carbohydrate molecules have been shown to slow the activity of neurons that would be interpreted by qEEG as a reduction in Z score (a measure of the activity of neurons in a specific brain area and less activity results in a lower Z-score).

Additionally, the Challenger stated that the criteria for enrollment of subjects in the study and associated exclusion criteria is absent in the testing protocol and that this can affect the observed data and conclusions in multiple ways:

- the presence of subjects with underlying health issues can introduce the potential for effects that would not be present in healthy individuals such as interaction with medications.
- the history of the use of CBD or other cannabis products in the individual test subject. Studies have shown that cannabis usage history can result in muted effects of CBD.

¹³ For example, MyDailyChoice maintained that there are no controls for vehicle (proprietary cyclodextrins) and that certain cyclodextrins have been shown to reduce Excitatory Junction Potentials which could be interpreted as a reduction in Z-score.

- the lack of a disclosed period of abstinence from the use of any cannabis or CBD product. The study summary suggests that each test subject did not consume a CBD product prior to observation, however, the exact period of time was not disclosed.
- the relationship of any test subject with any of the tested products. Any relationship with the tested products will produce expected results associated with a given product, especially if the subject was not blinded from all properties that would allow the subject to discriminate between products such as visual appearance, flavor, odor, mouth feel, etc. Expectations associated with a treatment will increase the likelihood of placebo effects.

The Challenger further maintained that, aside from identifying information for the test subject, the date and time of the performance of the experimental treatment and observation was absent or omitted from the study results.

MyDailyChoice also emphasized that BioReigns' testing data did not include the names of which products were tested nor indications of "eyes-open" and "eyes-closed" test conditions which resulted in a comparison of single observations which do not satisfy any reliable statistical method for determination of statistically significant changes.

Moreover, the Challenger contended that there was no indication as to when the tests were performed on each of the individuals and if the tests were performed on different days. In addition, differences in baseline measurements were not addressed by statistical normalization. MyDailyChoice added that the description of the experimental method did not show the dosage or method of standardization of dosage of each product provided to the test subject. The Challenger asserted that in well-designed experiments, dosage is standardized across test subjects as a function of milligrams of product per unit of body weight to control for differences in body size between individuals.

MyDailyChoice noted that BioReigns did not dispute that the EEG testing is investigatory and preliminary and maintained that BioReigns' claims are deficient for numerous reasons.

In sum, the Challenger pointed out that reliance on investigational and preliminary studies regarding EEG testing is insufficient to substantiate the Company's claims. The Challenger contended that BioReigns reference to five articles (two of which involved RCTs, and one study which was based on testing on rats) which it maintained discussed the benefits of EEG testing had no relevance to the flawed EEG testing submitted by BioReigns and that the studies do not meet the required substantiation standards defined by the FDA and FTC.

Doctor Endorsements in BioReigns' Videos

MyDailyChoice contended that the disclosure at the end of the videos stating that the doctors therein, "are being compensated by BioReigns or are affiliated with the

company by way of membership,” is not clear and conspicuous in disclosing the financial relationship between BioReigns and Dr. Juan Bautista (who provides a product endorsement) and is not close in proximity to the claims being made.

The Challenger also maintained that other videos featuring Dr. Bautista contain no such disclosure at all. More specifically, MyDailyChoice pointed to one video in which two physicians, Dr. Juan Bautista and Dr. J. Luis Bautista, are portrayed as objectively discussing the endocannabinoid system, the manner in which BioReigns’ products cross the blood-brain barrier, EEG testing and the purported benefits this confers in reducing neuro-inflammation and associated disorders. During the video, Dr. Juan Bautista states, “I’m a physician that doesn’t push a certain product, so I like patients to try new things out.” In addition, MyDailyChoice argued that the fine print disclaimer at the end of the video not only fails to disclose their financial relationship, it further suggests the Bautistas are providing an independent review. (e.g., “Discussions from doctors in this video are done from a 3rd party perspective based on their experience”).¹⁴

Accordingly, the Challenger argued that in each video featuring Dr. Juan Bautista or Dr. J. Luis Bautista, BioReigns must make appropriate audio and textual disclosures that “accompany the claim” (i.e. at the time the doctors are featured in the video), rather than at the end of the video in fine print after a pause signaling the video has ended.

Other General Product Claims

MyDailyChoice argued that other representations in BioReigns marketing materials (e.g., “vital to well-being,” “healing properties,” “boosts detoxification,” and “BioReigns gives you top of the line products in health, wellness, antiaging, weight loss, and fitness,” etc.) go much further than simply describing overall well-being and, conversely claim that its ingredients heal and detoxify, and suggest that BioReigns’ products have anti-aging, weight loss, and fitness properties. The Challenger argued that BioReigns is required to possess its own adequate substantiation for statements pertaining the specific efficacy of its products.¹⁵

B. Earnings Claims

MyDailyChoice contended that BioReigns’ marketing and advertising materials included inappropriate income claims. The Challenger referred several videos to DSSRC which it maintained emphasized recruitment instead of product sales.

MyDailyChoice called DSSRC’s attention to references being made in BioReigns advertising to building, “LONG-TERM residual income,” and, “... being paid through an INFINITE amount of levels.”

¹⁴ See <https://vimeo.com/386377623>

¹⁵ Additionally, MyDailyChoice reiterated its request that BioReigns be required to adequately support the claim for BioReigns CBD Lean product that it “may give you the boost you need to burn fat and lose weight.”

In addition, the Challenger pointed to claims such as, “[y]ou can live the life of your dreams, be your own boss, help others get healthier while you build residual income with our profitable and aggressive Distributor’s Compensation Plan and our innovative product line,” and, “[t]ake your business to the next level like never before with our Rank Bonuses and the Elite Expense Accounts.” The Challenger argued that these claims are improper and unsupported assertions regarding the typical amount of income that can be generally expected from the BioReigns business opportunity.

COMPANY’S POSITION

BioReigns explained that it offers a unique product line to consumers by offering the only true water dissolvable CBD complex. The Company explained that its products are formed with pharmaceutical technology used in circumstances of increasing vital water insoluble protein. The Company stated that, unlike competitive CBD products, there is no nanocomplex, which merely disperses small clusters (nano-size) of CBD molecules in an otherwise insoluble mixture and that eventually, all nano-complex ingredients will separate, like oil and water, providing minimal bioavailability.

A. Product Performance Claims

The Company took immediate, voluntary action to address many of the allegations raised by the Challenger. More specifically, BioReigns disabled a number of videos posted by Company distributors¹⁶ including videos which referenced the following terms and conditions:

- “pain,” “anxiety,” “depression,” “limiting cancer cell growth,” “epileptic seizures,” “Alzheimer’s disease,” “migraines and headaches.”
- “Perfect health solution,” “maximum bioavailability,” “proven with real people,” “eating and living well is not enough,” “increased mental clarity,” “less aches,” “joint support,” “immune support,” “weight management,” “more energy.”
- “100% availability,” “proven power of water-soluble CBD,” “anti-inflammatory,” “decreased inflammation,” “increased brain function,” “enhanced mental balance,” “improve sleep,” “improve cell health,” “stamina,” “mood enhancement,” “endurance,” “improve physical performance,” “increase body’s natural metabolic responses,” “more calories and fat being burned in support of weight loss goals,” “deeper sleep,” “muscle and joint relief,” “pain relieving salve,” “may relieve everyday aches and pains,” “pain relieving benefits of CBD,” “formula aids in skin cell regeneration not only on the face, but anywhere on the body.”

¹⁶ More specifically, BioReigns removed videos located at: https://lplayer.vimeo.com/_video/324841970; <https://vimeo.com/319594496;>
<https://vimeo.com/375309513;> <https://vimeo.com/375310545;>
<https://www.facebook.com/sumxoxos/videos/10157248105307872/?notifid=1580956218405166¬ift=live> video explicit, and : <https://www.youtube.com/watch?v=QzD7RqTrrJA>.

- CBD lean –“burn fat at a higher rate and maximizes results,” “more effectively burn through all of your carbs and proteins which will then allow your body to burn fat’,” “once you are in this state, you will have perfect energy, perfect focus and perfect fat loss,” “you will feel a difference with Bioreigns products, you will see the results, you will accomplish what everyone wants in life. A happier, healthier you.”

In addition to removing nine of the videos and posts at issue, BioReigns also made substantial modifications to a number of other videos and posts. For example, on the BioReigns website which lists the COAs, the Company added language at the top of the webpage stating that, “[t]hese test results are conducted on our raw materials and not our finished product,” in order to alleviate concerns that consumers may interpret the results as pertaining to BioReigns’ finished products.

With respect to statements regarding the superior bioavailability of its CBD products and the claim that the Company’s unique formulation allows its product to penetrate the blood-brain barrier to a greater extent than competitive, oil-based products, the Company explained that the challenge with hemp oil is that it’s lipophilic (i.e., oil-based) and when mixed with water, the oil simply floats on the top. Since water molecules are packed very tightly, oil molecules cannot incorporate into the water to form a solution and, therefore, the oil floats above the water. According to BioReigns, this is a challenge when creating oil-based nutrition products because nutrient absorption occurs primarily in the intestine and human intestinal cells are covered in a fine film of water which does not mix well with oil. The Company said that the net effect is that CBD oil flows straight past a person’s intestines and into the liver and is not delivered to the body as it should be.

As support for its claim that BioReigns’ products cross the “blood-brain barrier,” BioReigns provided DSSRC with EEG testing results on nineteen (19) individuals. EEG (also known as brain map testing) is a procedure that processes the recorded EEG activity from a multi-electrode recording using a computer. This multi-channel EEG data is processed with various algorithms, such as the “Fourier” classically, or in more modern applications “Wavelet” analysis. The digital data is statistically analyzed, sometimes comparing values with “normative” database reference values. The processed EEG is commonly converted into color maps of brain functioning called “Brain maps”. The EEG testing information can be interpreted and used by experts as a clinical tool to evaluate brain function, and to track the changes in brain function due to various interventions such as neurofeedback or medication.

Each subject was tested for a baseline score and was then tested after being administered a nanotech CBD product, an oil-based CBD product or the BioReigns water soluble CBD product. EEG data was then tabulated 5 minutes and 60 minutes after the product was administered. All subjects participated in two series of tests – once with their eyes open and once with their eyes closed.

BioReigns maintained that results of the testing which was conducted on a diverse group of subjects demonstrated the significant bioavailability of the primary ingredients in its products and that such products are shown to be active in the hippocampus, cortex and basal forebrain areas of the human brain.

The Company also maintained that its study provides proof that the product affects the brain and provided DSSRC several references to demonstrate the validity of its EEG testing as a valid and accepted testing protocol.

Raw ingredient testing

The Company also asserted that the accusation that its products do not contain CBD is patently false. As support for its position regarding the amount of CBD in the BioReigns' products that are sold to consumers, the Company provided DSSRC with laboratory testing results which BioReigns' maintained confirmed the presence of CBD in its finished products.

BioReigns further disputed the accuracy of MyDailyChoice's testing which purportedly showed only trace amounts of CBD in the Company's products and provided confidential testing to DSSRC which it maintained confirmed the presence of CBD in its finished products.

The Company asserted that it has gone above and beyond what its competitors do in order to obtain COAs by working with an independent third-party laboratory to ensure the technology involved in its products can be correctly measured. More specifically, BioReigns argued that its tests were conducted by an independent, analytical testing laboratory which has nearly twenty years of experience analyzing supplement, nutraceutical, food, and cosmetic compounds and specializes in botanical and nutritional analyses and uses approved chemical, biochemical, and wet chemistry techniques along with analysis of microbial contamination. BioReigns coordinated with the laboratory to develop tests appropriate to show the potency of water-based CBD, which many laboratories, including the one used by the Challenger, are not equipped to perform.

BioReigns disputed MyDailyChoice's allegation that BioReigns colluded with ABC Testing to falsify COAs noting that MyDailyChoice has not presented the DSSRC with any evidence of COA falsification. The Company maintained that the crux of MyDailyChoice's position is that BioReigns is "deceiving" the public because the various quality control standards it implements and deploys are different than process used by MyDailyChoice. According to BioReigns, the tests provided by MyDailyChoice that do not show detectable CBD in the products are themselves invalid and unreliable because they do not account for the delivery mechanism used by BioReigns' complex. The Company stated that its unique science requires specific standard operating procedures (SOPs) for CBD potency testing, and the BioReigns' lab coordinated carefully with chemists at a third party testing laboratory to develop more appropriate and more accurate testing

procedures.¹⁷ BioReigns informed DSSRC that on the revised COA documentation website page the Company now emphasizes that the test results refer to tests performed on raw materials and not the finished product.¹⁸ As a result of this change, BioReigns argued that it is now clear to consumers who view the webpage that contains the raw material COAs that these documents pertain only to BioReigns' raw materials (i.e., "These test results are conducted on our raw material and not our finished products") and noted that this is the only text in the body of the page other than the text in the analyses themselves. The Company argued, moreover, that the testing documents are not labeled with product names, but clearly labeled as "Broad Spectrum Distillate," "Isolate," and "Full Spectrum Distillate."

The Company also disputed the Challenger's argument that consumers will intentionally navigate to the webpage that includes testing results, but then fail to read or understand any of the words on that webpage.

The Company contended that although MyDailyChoice has made the commercial decision to disclose more information than is legally required with respect to supplement COAs, it has not identified a single legal obligation that requires BioReigns to do the same.

BioReigns stated that it has consistently informed consumers about the level of its proprietary BioCx complex in milligrams and objected to the Challenger's demands that these COAs "must" be published for public review. The Company noted that these COAs and product formulas are confidential and proprietary trade secrets, which BioReigns has invested heavily into developing and protecting. The Company stated that it is not aware of any legal authority that requires supplements to be analyzed for the content of specific ingredients, nor of any requirement that compels an entity to publicly disclose such trade secrets to its direct competitor, or to the public at large by online publication.

Other Performance Claims

BioReigns informed DSSRC that it has repeatedly communicated to independent sales representatives and staff that the only acceptable, compliant marketing language to be used must come directly from official company documents, messages, and videos. BioReigns stated that it has implemented steps to remove noncompliant and unauthorized communications and will continue to take immediate action to remove any posts that are not in compliance with Company policy and procedures. as well as to educate its salesforce about the gravity of unauthorized, noncompliant language.

¹⁷ In an effort to improve transparency BioReigns stated that it will list its ingredients in a way that makes the amount of the proprietary CBD blend, BioCx, clear.

¹⁸ BioDefense, is formulated to include ingredients scientifically linked to assist with immune system function. Similar to other companies in the industry, BioReigns added a specific COVID-19 disclaimer banner to its website, communicating to consumers that BioReigns does not believe that any of its products treat or cure COVID-19, or any other disease or illness.

With respect to the claim regarding Vitamin D3's ability to help the immune system, BioReigns stated that such claim simply communicates publicly available information that consumers can find on the internet and provided several studies to DSSRC as support for the claim.¹⁹ Moreover, the Company noted that the BioReigns video that references Vitamin D in scientific journals was made in an effort to educate the consumer about the potential efficacy of the ingredients in this product. Accordingly, BioReigns argued that MyDailyChoice portrayed the Vitamin D claims to DSSRC out of context. Notwithstanding the manner in which Challenger put the claims before DSSRC, BioReigns stated that it would voluntarily revise the video to provide greater clarification to consumers.²⁰

Regarding the Brain Derived Neurotrophic Factor (BDNF) ingredient in BioReigns' Limitless product, the Company disagreed with MyDailyChoice's assessment of the qEEG testing information arguing that the test itself, and the quality of the equipment and testing professionals involved, resulted in valuable information that should be shared with consumers.

The Company cited to a scientific study that it maintained supports the benefits of BDNF including BDNF in dietary supplements. The study stated that:

"[b]rain-derived neurotrophic factor (BDNF) plays an important role in activity dependent synaptic plasticity such as long-term potentiation. Recent experimental evidence supports the role of BDNF in memory processes: Memory acquisition and consolidation are associated with an increase in BDNF mRNA expression and the activation of its receptor TrkB. Genetic as well as pharmacologic deprivation of BDNF or TrkB impairs learning and memory... These findings suggest that BDNF/TrkB signaling in the hippocampus plays a crucial role in learning and memory."²¹

A second study referenced by BioReigns observed that:

¹⁹ Studies referenced by BioReigns specifically noting the link between Vitamin D3 and upper-respiratory infections included: Vitamin D Supplementation To Prevent Acute Respiratory Infections: Individual Participant Data Meta-Analysis. Health Technol Assess, Martineau AR, Jolliffe DA, Greenberg L, et al.. 2019;23(2):1–44. doi:10.3310/hta23020 ; The vitamin D connection to pediatric infections and immune function; Walker VP, Modlin RL. *Pediatr Res*. 2009;65(5 Pt 2):106R–113R.; Vitamin D increases the antiviral activity of bronchial epithelial cells in vitro. *Antiviral Res.*; 2017;137:93–101. doi:10.1016/j.antiviral.2016.11.004. <https://pubmed.ncbi.nlm.nih.gov/27838350/>; Vitamin D for prevention of respiratory tract infections: A systematic review and meta-analysis Charan J, Goyal JP, Saxena D, Yadav P. *J Pharmacol Pharmacother*. 2012;3(4):300–303. doi:10.4103/0976-500X.103685.

²⁰ BioReigns also maintained that MyDailyChoice was being disingenuous regarding its request that the Company list its substantiation for the general claims on the Company's website "promote better overall wellness" and "healing properties," noting that MyDailyChoice makes almost identical claims on the Hempwax website yet does not provide any supporting basis for the statements on the page where the claims appear.

²¹ Brain-Derived Neurotrophic Factor/TrkB Signaling in Memory Processes, Kiyofumi Yamada, Toshitaka Nabeshima; *Journal of Pharmacological Sciences*, 2003, Volume 91, Issue 4, Pages 267-270, Released April 21, 2003, Online ISSN 1347-8648, Print ISSN 1347-8613, <https://doi.org/10.1254/jphs.91.267>

“[a]mong all neurotrophins, brain-derived neurotrophic factor (BDNF) stands out for its high level of expression in the brain and its potent effects on synapses. It is now widely accepted that the main function of BDNF in the adult brain is to regulate synapses, with structural and functional effects ranging from short-term to long-lasting, on excitatory or inhibitory synapses, in many brain regions. ... The synergistic interactions between neuronal activity and synaptic plasticity by BDNF make it an ideal and essential regulator of cellular processes that underlie cognition and other complex behaviors. Indeed, numerous studies firmly established that BDNF plays a critical role in hippocampal longterm potentiation (LTP), a long-term enhancement of synaptic efficacy thought to underlie learning and memory. Converging evidence now strongly suggest that deficits in BDNF signaling contribute to the pathogenesis of several major diseases and disorders such as Huntington’s disease, Alzheimer’s disease, and depression...”²²

Additionally, BioReigns contended that MyDailyChoice is well aware of the scientific support for BDNF based upon the research it conducted in the development of its own CBD Coffeeberry Softgels which characterizes BDNF on the Hempworx website as, “a key neuroprotein involved in brain performance.”

Notwithstanding the Challenger’s assertions, in the spirit of voluntarily self-regulation, BioReigns agreed to revise the video at issue related to the qEEG testing, if necessary.

B. Earnings Claims

BioReigns removed the video stating, “[h]elp your three friends sell three elite packs to three new distributors each to receive your rank advancement to Elite 5k,” and made significant modifications to the second video that MyDailyChoice provided to DSSRC which it alleged included improper earnings claims.²³

In revising the video, BioReigns removed representations stating, “you will build LONG-TERM residual income. BioReigns has put together the most lucrative Binary pay structure in the industry. By paying out as much as 20% on your weaker leg volume, you are able to take advantage of being paid through an INFINITE amount of levels” and that “It is important to note that the Personal Qualifying Commission (PQV) is from your PERSONAL monthly order.” The Company changed the description of its Autoship Program by calling it “Smart Ship” and added language which notes that, “[t]his is a recurring order that you can automatically set up for shipment in your back office. This is NOT a requirement.”

BioReigns also changed the characterization of PQV from, “the monthly volume

²² BDNF and Synaptic Plasticity, Cognitive Function, and Dysfunction; Lu B., Nagappan G., Lu Y. (2014) In: Lewin G., Carter B. (eds) Neurotrophic Factors. Handbook of Experimental Pharmacology, vol 220. Springer, Berlin, Heidelberg

²³ <https://vimeo.com/375309513>

you personally need in order to stay Rank Qualified,” to a revised description that now includes qualifying language that, “[t]his volume can be obtained from both personal and retail orders.” The Company also removed language which stated that, “[y]ou can live the life of your dreams, be your own boss, help others get healthier while you build residual income with our profitable and aggressive Distributor’s Compensation Plan and our innovative product line. Take your business to the next level like never before with our Rank Bonuses and the Elite Expense Accounts.”

Generally, BioReigns disputed any suggestion that it is not taking its responsibility to the direct selling industry and to the public seriously. The Company asserted that it has complied with its obligations under the law with respect to the marketing and selling of its products and continues to do so.

BioReigns informed DSSRC that it has undertaken a wholesale review of its marketing materials, website and video content and has taken steps to further refine the quality and ensure the highest levels of accuracy for each. In addition, BioReigns stated that it has consulted with compliance experts, has begun working with a third-party monitoring vendor, and has developed refined marketing language to ensure the consistent publication of compliant communication and advertising by the company.

ANALYSIS AND RECOMMENDATIONS

As indicated by BioReigns at the outset of the inquiry, the Company has been in the process of revamping its marketing materials and the compliance oversight of its salesforce. DSSRC agreed that this organizational restructure was necessary and appropriate based upon the aggressive nature of the claims that were being disseminated by BioReigns at the time when this inquiry was commenced.

Based upon the actions taken by BioReigns throughout this inquiry to address the concerns raised by DSSRC and MyDailyChoice, DSSRC expressed its appreciation to the Company for its bona-fide and good faith efforts to bring its marketing materials into compliance with current rules and regulations.

More specifically, more than forty social media posts and videos were brought to the attention of BioReigns during the inquiry regarding product performance and business opportunity claims. The Company either removed or significantly modified each social media post, all but one video, two password protected videos and one group page. In addition, the Company made changes to the “Documentation” page on the Company’s website which shows COA testing conducted on the three forms of CBD sold by BioReigns (i.e., Full spectrum, isolate and broad spectrum) and to the “EEG Testing” section of the website.

However, notwithstanding the constructive changes made by BioReigns, DSSRC remained concerned with several remaining claims as well as with the reliability of the EEG testing and the consumer relevance of the resulting data.

A. Product Performance Claims

It is a fundamental principle of advertising law that an advertiser has the burden to possess a reasonable basis for any substantive claims communicated by its advertising and that all health-related claims must be supported by competent and reliable scientific evidence.²⁴ In addition, an advertiser has an obligation to support any express or implied claims that may be reasonably interpreted by consumers.²⁵

BioReigns EEG testing

BioReigns maintained that its development of a water-soluble delivery system increases the absorption of low bioavailability molecules in its product and maintained that its unique product formulation provides superior availability and penetrates the blood-brain barrier to a greater extent than oil-based products.

During the pendency of the challenge, BioReigns disabled videos which referenced the results of its EEG testing and removed videos from its website which depicted the brain mapping testing. DSSRC agreed that the voluntary actions taken by the Company were necessary and appropriate.

The only information currently on the “EEG Testing” page of the BioReigns website is a one-page summary of the BioReigns EEG test which described the protocol of the EEG testing.

According to the Company’s test report, most of the resulting brain waves’ z-scores were similar and within normal variance to the individuals’ baselines. More specifically, the testing report did not indicate that there was a significant (e.g., a statistically significant) change with any tested CBD oil or nano CBD product on any individual. Conversely, there was a consistent change indicating improvement in all brainwave area z-scores with the BioReigns water CBD product.

DSSRC notes that EEG studies record brain wave patterns and assess electrical impulses generated from brain neurons and how they communicate with each other. However, EEG testing does not measure subjective variables such as mental acuity, anxiety and depression. While DSSRC agreed with the Company that the EEG test results did indicate increased brain activity in subjects at both 5 minutes and 1 hour after being administered the BioReigns products, it remained concerned about the reliability of the testing results and the meaningfulness of the data as it was presented to consumers.

DSSRC determined that BioReigns’ representation that, unlike other competitive CBD products, the unique formulation in BioReigns’s products breaks the blood-brain

²⁴ 1983 FTC Policy Statement Regarding Advertising Substantiation

²⁵ See CCA Industries, Inc., (Nutra Nail Green Tea Treatment), Report #4805, NAD/CARU Case Reports (February 2008), quoting Freeman Beauty Labs (Renewance Anti-Aging Chemical Peel), Report #4543R, NAD/CARU Case Reports (September 2006)./

barrier around the brain, is a health-related claim necessitating reliable and competent scientific evidence as support.²⁶ DSSC also concluded that the results from the EEG studies could only be considered preliminary data and not the type of reliable and competent scientific evidence needed to support the claim. The Company's own marketing materials confirm the investigational nature of the EEG testing. For example, in several videos, Dr. Juan Bautista states that:

preliminary studies that were shown to me with the EEG studies showing that the CBD water crossed the blood-brain barrier within 5 minutes shows me again that this is bioavailable; it also shows me that if I'm trying to treat certain disorders again with neuroinflammation, that this is the type of product you want to be using.

DSSRC does not dispute that EEG testing can often produce encouraging and helpful data. However, for purposes of supporting the health-related claims at issue, the EEG testing results, alone, did not provide reliable evidence for the claims in the absence of well controlled clinical studies that corroborate the findings from EEG tests. For example, in a 2009 article in *Dementia & Neuropsychologia* entitled "The Clinical Use Of Quantitative EEG In Cognitive Disorders," the author notes that, "[t]here is an ongoing debate over routine use of qEEG," and that, "many findings regarding the clinical use of quantitative EEG are awaiting validation by independent investigators while confirmatory clinical follow-up studies are also needed."²⁷ Similarly, a 2017 article published in *Dementia & Neuropsychologia*, "Traumatic Brain Injury, An EEG point of View" discussed EEG findings in traumatic brain injury and concluded that, "[a]lthough the literature indicates the promise of qEEG in reaching a diagnosis and indicating prognosis of [mild]TBI, further study is needed to corroborate and refine these methods."²⁸

Although, BioReigns did provide certain information regarding the parameters and protocol of the EEG testing (including a video of how the test was administered to three subjects), DSSRC remained unpersuaded regarding the reliability of the study. For example, unlike the reporting of data from well-controlled clinical testing, there was no indication in the testing protocol that the EEG results were statistically significant or consumer relevant. The only information that was provided regarding the significance of the testing results was a comment in the testing report that:

²⁶ POM Wonderful v. FTC, (DC Circuit Court of Appeals 2015) at https://www.ftc.gov/system/files/documents/cases/pom_dc_circuit1_0.pdf; InterHealth Nutraceuticals, Inc. (Zychrome), Report #5569, NAD/CARU Case Reports (April 2013).

²⁷ See Dement Neuropsychol. 2009 Jul-Sep; 3(3): 195–203. Clinical use of qEEG can be problematic particularly in the hands of untrained operators. The statistical results can be influenced by wrong electrode placement, artifact contamination, inadequate band filtering, drowsiness, comparisons using incorrect control data bases, and choice of epochs.⁵ Furthermore, statistical processing can yield a large numbers of statistical abnormalities, not all of which are of clinical relevance. These are some reasons, despite the volume of published data, that the clinical usefulness of qEEG remains controversial.

²⁸ Dement Neuropsychol. 2017 Jan-Mar; 11(1): 3–5.

our test results showed that most of the resulting brainwaves' z-scores were similar and within a normal variance to the individuals' baselines as follows:

- There was no significant change with any tested CBD Oil Product on any individual
- There was no significant change with any tested Nano CBD product on any individual
- There was however, a consistent change indicating improvement in the brainwave area z-scores... with the Water CBD product.

With respect to testing methodology, there was no indication regarding which BioReigns products was used in the testing and neither the subjects or test administrators were blinded during the administration of the study.²⁹ Moreover, DSSRC was concerned that the BioReigns product and the competitive oil or nanotech formulas were not administered pursuant to product usage directions. For instance, in the testing video that demonstrated how the EEG testing was conducted on three subjects, the test administrator had her back turned while one test subject was applying the product. In another scenario, the test subject was given five droppers of BioReigns, which appeared to be inconsistent with product usage instructions (i.e., “place full dropper (1 mL) under your tongue daily”). Similarly, many competitive oil and nano products instruct users to shake the CBD the bottle well before using it. However, the test administrators who appeared in in the video did not appear to provide appropriate usage instructions to test subjects when they were taking the competitive products.³⁰

Although the test report stated that tests were performed, “on different days and subjects,” there was no further information provided in the individual data reports for the subjects regarding the dates or times when each subject was tested. The lack of information was troubling to DSSRC because accounting for an adequate washout period between administration of products would be critical in evaluating the effects of the tested product. In the video which demonstrated how the EEG testing was conducted, the test subjects were given the BioReigns CBD product approximately five minutes after being administered the competitive product which raised a question of whether some of the positive data from use of the BioReigns product may have been attributable to the delayed effects of the competitive product which was administered five to ten minutes earlier. In addition, DSSRC questioned whether the positive data for the BioReigns products may

²⁹ DSSRC was concerned that test subjects and test administrators knowing which products were being evaluated could have significantly compromise the results. For example, on the BioReigns EEG testing video provided to DSSRC, one subject was heard asking about when they may feel an effect from the BioReigns formula. The test administrator told the subject that she would be feeling an “immediate benefit.”

³⁰ When one test subject asked the study administrator how much product she should take, the test administrator replied – “1 drop... whatever you want.”

have been the result of the efficacy of ingredients other than CBD that are present in the tested formula such as curcumin or the BioCx Proprietary Complex.

Finally, there was no information provided on how the respective products would perform on healthy individuals. It appeared that all of the test subjects had pre-existing mental defects before the tests were conducted ranging from impaired memory to fibromyalgia. According to the FTC, advertisers should not rely on research based on a specific test population for claims targeted at the general population without first considering whether it is scientifically sound to make such extrapolations.³¹ As such, DSSRC could not appropriately ascertain the anticipated effects of the products on healthy subjects and concluded that the EEG testing could not serve as adequate substantiation for a claim about maintaining a healthy state because the studies' populations are different from the intended population in the claim.

For these reasons, DSSRC concluded that the Company's removal of references in its marketing materials and on its website to the results of its EEG testing as support for its claim that the CBD molecules in BioReigns penetrate the blood-brain barrier were necessary and appropriate.

BioReigns Raw Ingredient Testing and the Presentation of COAs

A COA is a laboratory report on the chemical make-up (e.g., contents) of a product or ingredient and reports on the cannabinoid, terpene, and contaminant profile of CBD products or ingredient. On the "Document" page in the "About" tab of the BioReigns website, the Company displays three COA reports that were conducted on the raw ingredients contained in BioReigns Broad Spectrum, Isolate and Full Spectrum formulas.

MyDailyChoice argued that BioReigns posted these reports to support claims about its products' purity and noted that the posted test results are actually for the raw feed stock for the product and not for the finished product. Shortly after commencement of the inquiry BioReigns modified the "Document" page of the website to disclose on the top of the page that, "[t]hese test results are conducted on our raw material and not our finished products."

DSSRC agreed with MyDailyChoice that the original, unqualified presentation of the raw ingredient COAs on the "Document" page of the website BioReigns could send an inaccurate message to consumers who could reasonably interpret the information presented in the COAs to pertain to the finished product and not the raw feed stock used to produce BioReigns products. Although the Company's addition of disclosure language to the webpage during this inquiry that COA test results were, "conducted on our raw material and not our finished products," did demonstrate a good faith effort on the part of BioReigns to clarify what the COAs pertained to, the issue for DSSRC to consider is whether this modification was a meaningful one for consumers in their interpretation of the depicted information.

³¹ <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry#>

While COAs provide greater transparency for consumers as well as regulators and help identify what is and what is not inside a given CBD product, DSSRC is not aware of any requirement that a CBD Company is obligated to provide or display COA's for its products and/or ingredients. However, DSSRC agreed with MyDailyChoice that if a Company provides a COA in its marketing materials it should do so in a way that is clear and unambiguous to consumers.

Here, while the COAs do provide useful information regarding the ingredients that are used in the product from the purity and potency of the ingredients to other potentially harmful contaminants, there is no assurance that the same level and percentage of cannabinoids that exist in the ingredient are also be present in the final product. For example, CBD extraction is the method used to isolate CBD from the plant and separate it from the other cannabinoids that are present and the method of extraction and can impact the purity of the final product. Further, depending on the manufacturing process, the amount of CBD that a CBD water formula contains can be significantly compromised when it is exposed to light for an extended period of time, such as being stationary in a storage facility all day. Similarly, as is the case with drug products and dietary supplements, the presence of other ingredients in the products may offset the potency and effectiveness of an active or primary ingredient.

BioReigns did provide confidential testing from an outside laboratory regarding the presence of CBD in three of its products. Although MyDailyChoice provided rebuttal testing indicating the lack of any detectable CBD in certain BioReigns' products, BioReigns questioned the reliability of the Challenger's testing because it did not account for the delivery mechanism used by BioReigns' complex and because of the specific operating procedures necessary to evaluate unique water soluble delivery mechanism.

The quality of many CBD products has been the subject of debate in the industry. The FDA has expressed concern that a lack of appropriate processing controls and practices has resulted in a significant amount of consumer confusion in the marketplace regarding the accuracy of the amount of CBD that is contained in many CBD products. The agency has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed.³² In addition, a 2017 study by a Penn Medicine researcher of 84 CBD products sold by 31 companies online, found that nearly 70 percent of all cannabidiol products sold online are either over or under labeled, which corroborated the results of a similar 2015 study.³³

Accordingly, DSSRC remained concerned that the potency and purity of the CBD in the raw materials used during the processing of ingredients may be significantly different than the amount of CBD contained in the final product.

DSSRC acknowledged that BioReigns did modify its Documentation page to include

³² See <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>.

³³ Labeling Accuracy of Cannabidiol Extracts Sold Online, Marcel O. Bonn-Miller, PhD, Mallory J. E. Loflin, PHD; Brian F. Thomas, PhD; et al, JAMA. 2017; 318 (17) 1708-1709.

the disclosure stating that “These test results are conducted on our raw material and not our finished products” above the three COAs. Notwithstanding this change DSSRC remained concerned that consumers may still take away the implied message that the potency and purity of the ingredients as reported in the COAs would be the same potency and purity of the ingredients as contained in the final product. BioReigns did not provide adequate support for such a message.

Advertisers are responsible for ensuring that all express and implied claims that an ad conveys to reasonable consumers are truthful and substantiated. If an ad makes express or implied claims that are likely to be misleading without certain qualifying information, the information must be disclosed. A disclosure can only qualify or limit a claim to avoid a misleading impression. It cannot cure a false claim.³⁴

In the absence of consumer perception evidence, self-regulation programs administered by BBB National Programs will use its expertise to determine the express and implied messages reasonably conveyed in an advertisement.³⁵ In analyzing the messages conveyed by a particular claim or advertisement, DSSRC typically reviews the net impression created by an advertisement as a whole.

DSSRC concluded that the COA of the raw materials could provide useful information regarding the quality of ingredients in BioReigns raw materials but the simple disclosure that the test results were conducted on our raw material and not our finished products was not sufficient to put consumers on notice that presence of CBD in the ingredients would not correlate to the same potency and purity of the CBD that is contained in the final product. As such, DSSRC recommends that the Company modify the disclosure to clearly and conspicuously indicate the utility of presenting the COAs for the raw materials used in its products and make clear that the percentage of CBD contained in the final product can vary significantly.

Other Claims at Issue

MyDailyChoice called DSSRC’s attention to several other claims made by BioReigns that it alleged were not supported by the appropriate evidence.

As a general principle, advertisers must have a reasonable basis for advertising claims before they are disseminated. Objective claims for products or services represent explicitly or by implication that the advertiser has a reasonable basis supporting these claims. These representations of substantiation are material to consumers. That is, consumers would be less likely to rely on claims for products and services if they knew the advertiser did not have a reasonable basis for believing them to be true. Failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in

³⁴ Federal Trade Commission’s dot.com Disclosures Guide: How to Make Effective Disclosures In Digital Advertising. Page 5.

³⁵ Geerpress, Inc.. (ADVANTEX Single-Use Disposable Micro-Fiber Mop Pad), Report #6340, NAD/CARU Case Reports (January 2020).

violation of Section 5 of the Federal Trade Commission Act.³⁶

As noted earlier in this decision, during the pendency of the challenge BioReigns removed a number of express product performance claims that were being made by its sales force including (but not limited to) general claims that the Company's products can alleviate pain, decrease inflammation, improve stamina and endurance, provide deeper sleep and burn more calories and fat. BioReigns also removed a number of serious disease and health related claims either expressly claiming or implying that the Company's products are effective against epileptic seizures and Alzheimer's disease, can limit cancer cell growth, improve cell health and aid in skin cell regeneration not only on the face, but anywhere on the body.

In addition, it appears that BioReigns has removed almost all of the claims regarding the bioavailability of its formulation, although DSSRC did identify one consumer website which includes videos referencing BioReigns "maximum bioavailability" and "100% availability" with respect to its CBD ingredient.³⁷

DSSRC agreed that the Company's actions to remove these express and implied claims were necessary and appropriate.

BioReigns did provide EEG testing which did show increased brain wave activity after the BioReigns product was administered, however, as noted above, the EEG testing results could only be considered preliminary and DSSRC was not persuaded that these testing results were could serve as a reliable indicator of product performance results that could be expected by consumers particularly with respect to the specific efficacy and health-related claims that were the subject of this challenge.

For example, the omission of reliable, well controlled testing on BioReigns products would make claims regarding the bioavailability of its products untenable. Conceptually, DSSRC recognized the validity of the Company's explanation that because cannabinoids are lipophilic molecules (i.e., oil-based compounds that are not soluble in water) when you place extracted hemp oils into water, they float and do not mix or dissolve in the water. Accordingly, because the human body is made up of approximately 60% water cannabinoids have difficulty dissolving, and more importantly, absorbing these types of molecules. Notwithstanding this reasoning, any BioReigns claims of "100% availability" must be supported by specific evidence demonstrating that the CBD in the product is bioavailable to the extent promised by the claims. Similarly, unqualified claims of superior comparative bioavailability (i.e., oil) would necessitate reliable testing of the advertisers own product as well as a representative sample of competitive products on the market using the same vehicle of administration (e.g., tincture, spray topical, etc.) and usage instructions as indicated on the products' labeling.

³⁶ 1983 FTC Policy Statement Regarding Advertising Substantiation.

³⁷ See <https://www.facebook.com/groups/TheBioreignsExperience/>

BioReigns did not provide any additional testing on any of its products nor on any of the ingredients at the same dosage level at which they are contained in the product. Although the Company did provide a COA of sixteen of its products and displays COAs for the raw materials used in the three BioReigns products, the COAs only reported the purported presence of CBD and other ingredients in the products and did not evaluate how the products or ingredients performed in situations of normal product usage.

In the absence of testing on the product itself and depending on the context in which the claim is presented, an advertiser can rely on testing of individual ingredients to support general performance claims regarding product efficacy however, even in such situations, an advertiser should clearly attribute the efficacy to the ingredient and not the product itself. For example, in a case before BBB National Programs' National Advertising Division (NAD) involving claims for a stem cell therapy cream that were based on the active ingredient in the product, NAD noted that it has consistently held that testing on individual ingredients in a product that show some effect is generally insufficient to prove that a combination of those ingredients would have the same, or any, effect absent reliable evidence that would permit such extrapolation.³⁸ Accordingly, when there is substantiation only for the efficacy of ingredients in a product, but not for the product itself, the claims must be clearly expressed as ingredient claims.

Although BioReigns did explain that the products are formulated to include ingredients scientifically linked to assist with immune system function, there was no testing provided indicating that the product ingredients are efficacious at the dosage level in which they are present in BioReigns products. Without such information, DSSRC was unable to appropriately assess the efficacy of the ingredients and evaluate how the product performs in normal conditions of use.

BioReigns did cite to a number of published articles and studies regarding the generally efficacy of ingredients in BioReigns, however, many of the references could only be found in summary abstracts and the Company did not produce the actual studies or articles. Moreover, the Company could not confirm that any of the articles or studies evaluated the particular ingredient at the dosage level in which they are present in BioReigns products.

For example, BioReigns referred DSSRC to four published articles regarding Vitamin D3's ability to help the immune system. Two of the articles were metanalysis' that examined data from a number of independent studies conducted on Vitamin D and D3. The third article discussed the administration of Vitamin D in children and the fourth article reported on in-vitro findings of increased antiviral activity of bronchial epithelial cells when

³⁸ Biological Solutions, Inc., (Stem Cell Therapy Cream), NAD Case Report #3568 (8/24/11).

Vitamin D was added to the culture. However, none of the studies were provided in full to DSSRC.³⁹

DSSRC determined that without evaluating the parameters of the studies that are included in the meta-analysis that was the subject of several of the articles, the relevance of studies to the performance claims at issue in this challenge could not be properly ascertained. Similarly, DSSRC was not persuaded that in-vitro testing and testing conducted on children could support claims targeted to an adult audience. For all of these reasons, DSSRC could not properly evaluate the relevancy of the published articles on Vitamin D or how Vitamin D contributes to the efficacy of the Company's products.

When making claims based on the ingredients in a product, an advertiser bears the burden of demonstrating that its product has the same ingredient in the same dosage, formulation, and route of administration as the underlying studies submitted in support of its health claims.⁴⁰

In sum, if the Company intends to make any general or health-related performance claims for its products, it is incumbent on BioReigns to possess reliable and competent evidence demonstrating that the product performs as claimed. In the omission of such evidence, DSSRC concluded that BioReigns could not support the performance claims at issue.

Marketing for BioDefense

Shortly after the COVID-19 outbreak in the United States, BioReigns introduced BioDefense which, according to the Company website, “[h]elps your immune cells fight pathogens by stimulating and enhancing their natural defensive processes. EGCG can increase the power of Natural Killer immune cells to destroy pathogens, and 1,3-β D-Glucan can enhance the function of macrophage cells, which engulf and digest foreign substances in the body.”

Members of the BioReigns salesforce were given access to a short video regarding the purported benefits of BioDefense which features Dr. Juan Bautista. The Challenger argued that the video contains unsupported claims for the products including an implied message that the product can protect against the coronavirus. BioReigns disputed the Challenger's allegations and noted that the video makes no express reference to the virus and that consumers would not understand the video as communicating that BioDefense is effective against the corona virus.

³⁹ See The FTC's Dietary Supplements: An Advertising Guide for Industry. The FDA has articulated, in its guidance to industry for dietary supplement advertising claim support, the scientific consensus regarding the evidentiary value of animal and in vitro studies: Animal studies may provide useful background on the biological effects of a substance. However, they often have limited or unknown value in predicting the effect of the substance in humans. Care should be exercised in extrapolating results obtained in animal research directly to the human condition . . . without any data from human studies, the results of animal studies alone are not sufficient to substantiate a claim.

⁴⁰ Wink Naturals, LLC (Wink Nationals Sleep Products) NAD Case Report #6285 (6/13/19).

The video begins with the statement that, “[w]e’re all exposed to harmful germs and bacteria everyday,” and then shows close-up images of various virus particles. The video continues by asking, “[h]ow do we defend our body from the pathogens all around us?” Dr Bautista then appears on screen and states:

there is no way to guarantee that we will never suffer from a specific infectious disease but there are steps that we can take to generally protect ourselves. Like coughing and sneezing into disposable tissues, frequently washing our hands with soap and not touching our face, but for people who want to do more than this, BioReigns is offering BioDefense....for an extra layer of defense against potential harmful agents.

Dr Bautista then discuss the effectiveness of the individual ingredients in BioDefense including curcumin, 1,3-β D-Glucan and EGCG. While he is speaking, quotations from studies conducted on these ingredients appear on the screen, including statements such as:

The inhibitory effects of EGCG on multiple viruses indicates that this compound is a potential alternative for viral diseases” and “B-Glucan exhibits many biological activities and functions such as stimulation of the immune system and anti-inflammatory, including anti-microbial anti-virus, anti-infective, anti-viral, anti-tumor, anti-oxidant, anti-coagulant, cholesterol-lowering, radio protecting and wound healing effects.

Dr. Bautista goes on to state that:

These molecules may bring ant-oxidant benefits to your body and may also help your liver, your blood vessels and your heart and stimulate your immune system. They boost the ability of specific cells in the immune system to better destroy pathogens...and increase your resistance to infection...enhance mood and decrease vulnerability to infection.

As noted above, an advertiser has an obligation to support any express or implied claims that may be reasonably interpreted by consumers.⁴¹ DSSRC agreed that the video does not specifically mention COVID-19 or the coronavirus. However, DSSRC determined that based upon references to the exposure to harmful germs and bacteria, the recitation of Center for Diseases Control recommendations to help protect against the coronavirus (e.g., frequent washing of hands, not touching the face, coughing into a tissue) and the suggestion that for people who want to do more than this, BioReigns provides, “an extra layer of defense against potential harmful agents,” accompanied by images of virus particles that look similar to COVID-19, the video could be reasonably interpreted by consumers as meaning that BioDefense offers additional protection against the coronavirus. DSSRC also recognized that the product and the video first became available in the middle of March, the time when the spread of the coronavirus was

⁴¹ *Supra* at 28.

reaching epidemic proportions. Finally, DSSRC concluded that Dr. Bautista's brief statement early in the video that, "there is no way to guarantee that we will never suffer from a specific infectious disease," would not be considered a clear or conspicuous disclosure to consumers that the product is not effective against the coronavirus.

With respect to the disclosure at the end of the video regarding Dr. Bautista's association with BioReigns, ("[d]iscussions from doctors in this video are done from a 3rd party perspective based on their experience"), DSSRC agreed with the Challenger that the disclosure at the end of the video did not adequately disclose the material connection of Dr. Bautista with the Company. DSSRC appreciated the effort to modify the disclosure to state the, "the doctors in this video are being compensated by BioReigns or are affiliated by the company by way of membership." Notwithstanding this change, DSSRC determined that the one-time disclosure at the end of the video could not be considered clear and conspicuous. Accordingly, DSSRC recommends that should BioReigns use expert endorsements who have a material connection to BioReigns in any future promotional videos, the Company should provide a clear and conspicuous disclosure regarding the endorser's association with BioReigns at the time the endorser appears on the video. According to the FTC, to make a disclosure clear and conspicuous, the disclosure should accompany the claim.⁴²

Finally, DSSRC reviewed the product description on the Company website that Bio Defense, "[h]elps your immune cells fight pathogens by stimulating and enhancing their natural defensive processes. EGCG can increase the power of Natural Killer immune cells to destroy pathogens, and 1,3-β D-Glucan can enhance the function of macrophage cells, which engulf and digest foreign substances in the body." Despite the references to certain ingredients in Bio Defense providing the purported benefits, DSSRC determined that the statement would be interpreted by consumers as meaning that product itself will perform as claimed. As noted by the NAD in previous decisions, the fact that the individual ingredients of a combination product have been deemed to be effective does not by itself establish the basis for . . . claims about the product"⁴³ In this inquiry, BioReigns provided no evidence demonstrating that the product can provide the stated benefits or that the individual ingredients (i.e., at the same dosage level in which they are present in Bio Defense) can deliver the benefits stated in the product description.

⁴² *Supra* at 36. DSSRC also notes that disclosures regarding the material connection of product endorser should provide the necessary specificity regarding the nature of the connection between the endorser and the advertiser. For example, when only one doctor appears in the advertisement, a disclosure stating that "the doctors in this video are being compensated by BioReigns or are affiliated by the company by way of membership" may be interpreted ambiguously by consumers who may remain uncertain about the relationship of the doctor with the Company.

⁴³ Den-Mat Corp (Rembrandt Plus Superior Bleaching System and Dazzling White Tooth Bleaching Value Kit), Report #3814, NAD/CARU Case Reports (September 2001); See also, Den-Mat Corp (Rembrandt Age Defying Adult Formula Toothpaste), Report #3527, NAD/CARU Case Reports (March 1999); Abbott Nutrition (Similac Advance and Similac NeoSure Infant Formulas), Report #4849, NAD/CARU Case Reports (May 2008). Colgate-Palmolive Company (Colgate Optic White) Report #5490 NAD/CARU Case Reports (July, 2012).

Similarly, on the product page on BioReigns' website below the product description there is a "Key Ingredients and Functions" section that provides information on the various benefits that these ingredients contribute to overall product efficacy. For example, the "Key Ingredients and Functions" section on the Bio Defense page states that curcumin is, "an extract of turmeric that can help the body manage pain, stress, and inflammation." While it may be true that curcumin has been shown to provide such a benefit at certain dosage levels, there is no evidence in the case record demonstrating that the amount of curcumin in a recommended dosage of Bio Defense will confer the stated benefit. In the absence of this evidentiary support, DSSRC determined that BioReigns could not support the statements on the website pertaining to the efficacy of the product's ingredients.

As such, DSSRC recommended that BioReigns remove statements on the website stating or implying that Bio Defense and/or its ingredients can fight and destroy pathogens and enhance the function of macrophage cells until such time that it possess competent and reliable evidence demonstrating that the product (or the ingredients contained in the product) can provide the benefits enumerated in the description of the product. In addition, DSSRC recommends that the Company review the "Key Ingredients and Functions" section for all of the products on its product website so that the information communicated to consumers is consistent with the available evidence for the ingredient at the dosage level in which they are present in BioReigns products.⁴⁴

CONCLUSION

In a demonstration of good faith, BioReigns voluntarily removed or modified more than forty social media posts and videos during the pendency of this challenge including general claims that the Company's products can alleviate pain, decrease inflammation, improve stamina and endurance, provide deeper sleep, and burn more calories and fat. BioReigns also removed a number of express and implied disease and health-related claims. DSSRC agreed that the voluntary actions taken by the Company were necessary and appropriate.

In addition, DSSRC concluded that BioReigns did not provide adequate support for its bioavailability and "breaking the blood-brain barrier" claims. With respect to the COAs on the BioReigns website, DSSRC determined that although the COAs of the raw materials could provide useful information regarding the quality of ingredients in BioReigns raw materials, its disclosure that the test results were conducted on our raw materials and not our finished products was not sufficient to put consumers on notice that presence of CBD in the ingredients would not correlate to the same potency and purity of the CBD that is contained in the final product. DSSRC recommends that the Company modify the disclosure to clearly and conspicuously indicate the utility of presenting the COAs for the raw materials used in its products and make clear that the percentage of

⁴⁴ DSSRC notes that conclusions or recommendations made in this inquiry are also applicable to any representation disseminated on any password protected websites that are owned or controlled by BioReigns.

CBD contained in the final product can vary significantly.

DSSRC also recommended that BioReigns remove statements on the website stating or implying that Bio Defense and/or its ingredients can fight and destroy pathogens and enhance the function of macrophage cells, DSSRC also recommended that should BioReigns use expert endorsements by individuals who have a material connection to BioReigns, the Company should provide a clear and conspicuous disclosure regarding the endorser's association with BioReigns at the time the endorser appears on the video.

Finally, DSSRC recommended that the Company review and revise the "Key Ingredients and Functions" section for all of the products on its product website so that the information communicated to consumers is consistent with the available evidence for the ingredient at the dosage level in which they are present in BioReigns products.

COMPANY STATEMENT

"BioReigns sincerely appreciates the DSSRC's efforts to help us improve compliance with regulatory and direct selling industry standards. The company appreciates and agrees with the DSSRC's assessment that BioReigns takes transparency and public education about our products very seriously. The steps BioReigns has already taken since our communications with the DSSRC began demonstrate how readily we respond to compliance guidance from both our internal consultants and external organizations.

BioReigns strives to provide the best information available about the ingredients in our products, and about our products themselves. The company believes strongly in empowering consumers to make the best decisions they can for their health and wellness. Please be assured that BioReigns will continue to move forward with, and aim to implement, your recommendations to support the DSSRC's mission of a direct selling industry "conduct[ed] with the highest level of business ethics."

(Case No. 22-2020 PCM, closed on 07/24/20)

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