United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 9, 2019

VIA FEDERAL EXPRESS
Jared Forbush
4Bush Holdings, LLC
318 West 250 South
Kaysville, UT 84037-2443

Dear Mr. Forbush:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you may be making false or unsubstantiated advertising claims about the health benefits of products containing cannabidiol (CBD), a chemical compound derived from the cannabis plant..

Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, prohibit unfair or deceptive advertising. Specifically, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made. This substantiation requirement applies whether the advertiser disseminates such health claims directly via traditional advertising or indirectly via the use of a product name, website name, or metatags. This requirement also extends to consumer endorsements. It's not enough that an endorsement represents the consumer's honest opinion or experience. Reasonable consumers may interpret an endorsement claiming a health benefit from the use of a product as representing that the product is likely to be effective in achieving that benefit. Under FTC law, an advertiser must possess and rely on competent and reliable scientific evidence to support health claims, both express and implied, made through the use of endorsements.

FTC staff has reviewed your websites, including www.magicgreenoildrops.com, for potential violations of the FTC Act. We are concerned that one or more of the health benefit claims excerpted below may be false or not substantiated by competent and reliable scientific evidence.

Excerpts from www.magicgreenoildrops.com

Complete Relief CBD - Clinically Validated Cannabidiol

* * *

SPECIAL REPORT: Woman Paralyzed By Pain Discovers Breakthrough Relief Called 'Nature's Oxycontin'....

Complete Relief CBD has been called "Nature's Oxycontin" because it **quickly relieves even the most agonizing pain**.... **Many say it works like magic.** Some say it works better than prescription painkillers like Vicodin and Oxycontin....

* * *

[Dr.] Jamie [Richardson] applied for a research grant to run the first ever **FDA approved clinical trial involving CBD**.
With the help of **Harvard researchers and medical doctors**, Jamie led a clinical trial studying the effects of CBD on pain and inflammation.
The results were astonishing. Through their research, they discovered a multitude of other health benefits of CBD they never anticipated. Richardson's team ran additional follow-up studies that concluded CBD is nothing short of a real medical miracle.

CBD has now been clinically proven to:

* * *

Reduce social anxiety, cognitive impairment, and discomfort in patients diagnosed with Generalized Social Anxiety Disorder (SAD)
Decrease cancer spread by "turning off" genes involved in tumor development
Combat neurodegenerative disorders like Alzheimer's by removing plaque that block neuron-signaling
Reduces cigarette addiction by modulating the rewarding the effects of nicotine
[R]estore respiratory stability to those experiencing sleep Apnea
Clears acne by inhibiting lipid synthesis on the skin
Regulates blood sugar and lowers insulin resistance
Provide relief to those suffering from IBD (Chron's [sic] or Colitis) through its anti-inflammatory effects
Improves symptoms of MS (multiple sclerosis) by providing durable protection to neurons
Prevents obesity....

[Dr. Jamie Richardson] teamed up with his group of Harvard researchers to create Complete Relief CBD, a brand of medical grade CBD supplements developed through thousands of hours of research and clinical trials....

All 5 [venture capital investors from the television show *Shark Tank*] jumped on the opportunity to invest in Complete Relief CBD with confidence, calling it the...

"Natural Miracle Cure That Will Bring Down Big Pharma"

* * *

Morgan Freeman: "The Only Thing That Offers Relief For Fibromyalgia is CBD"

* * *

[O]ur senior editor Tanya Johnson volunteered for our experiment.
Tanya was chosen because of her history with Rheumatoid Arthritis, a painful autoimmune condition doctors don't yet have a complete cure for.

Below is her story...

Tanya's Real Life Experience With Complete Relief CBD...

One day, while watching an episode of The Doctors, I heard Dr. Travis Stork talk about a natural solution to pain management and inflammation that's even more effective than prescription meds. Of course, the solution was CBD and the brand he recommended was Complete Relief CBD.... So I decided to order a risk-free sample and give it a shot.

Within a few weeks, my pain completely disappeared and my normal panic attacks began to subside.... I not only saved thousands of dollars, but also the hassle of doctor visits and therapy sessions thanks to Complete Relief CBD.

* * *

Get a Risk-Free Trial Today>>

* * *

Finally a Cannabidiol Supplement that is medically validated and absolutely legal!

Excerpts from www.offer.firstclassherbalistcbd.com[...], Linked from the "Get a Risk-Free Trial Today" Button

The Science of CBD (CANNABIDOIL)

* * *

CBD Oil has been medically proven to positively regulate your endocannabinoid system] addressing issues such as... hypertension[] and even cardiovascular issues....

- **Psychological Benefits:** .... [I]n some cases may offer a safe remedy for depression and bipolar disorders.

- **Neurological Benefits**: Our CBD Oil's positive impact on the neural system helps reduce age-related cognitive decline....

REAL SUCCESS STORIES!

"After a big cancer scare, I started taking CBD about 6 months ago and LOVE IT! My Oncologist said whatever you are doing to keep doing it. I have used a few brands and my favorite is by far Herbalist Oils CBD. My energy is slowly coming back and I feel wonderful."

- Kandi

We strongly urge you to review all claims for your products, including consumer testimonials, and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a federal district court injunction or an administrative cease and desist order. An order also may require that you refund money to consumers.

With regard to the advertising claims discussed above, please notify staff attorney Keith Fentonmiller via electronic mail at kfentonmiller@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC staff's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Fentonmiller at 202-326-2775.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 9, 2019

VIA FEDERAL EXPRESS
NuLife CBD Oils, LLC
1000 Continental Dr.
King of Prussia, PA 19406

To Whom It May Concern:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you may be making false or unsubstantiated advertising claims about the health benefits of products containing cannabidiol (CBD), a chemical compound derived from the cannabis plant..

Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, prohibit unfair or deceptive advertising. Specifically, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made. This substantiation requirement applies whether the advertiser disseminates such health claims directly via traditional advertising or indirectly via the use of a product name, website name, or metatags. This requirement also extends to consumer endorsements. It's not enough that an endorsement represents the consumer's honest opinion or experience. Reasonable consumers may interpret an endorsement claiming a health benefit from the use of a product as representing that the product is likely to be effective in achieving that benefit. Under FTC law, an advertiser must possess and rely on competent and reliable scientific evidence to support health claims, both express and implied, made through the use of endorsements.

FTC staff has reviewed your website, www.nulifecbdoils.com, for potential violations of the FTC Act. We are concerned that one or more of the health benefit claims excerpted below may not be substantiated by competent and reliable scientific evidence.

Excerpts from www.nulifecbdoils.com/medical-applications-cbd

The Health Applications of CBD

The Many Ways in Which CBD is Increasing Health and Enhancing Lives

The cannabinoid compound, cannabidiol – otherwise known as CBD, is becoming increasingly respected and acknowledged as a powerful healing modality that treats a wide spectrum of medical conditions. With it's low to zero THC content, CBD offers powerful pain relief without the psychotropic effects of feeling "high" that go along with recreational marijuana. Extensive research has gone into the different ways in which CBD affects the endocannabinoid system of the body that regulates our immune system, sleep, nervous system and organ functions. CBD can be used to combat a wide range of medical issues and there are miraculous and positive testimonials in abundance that highlight CBD success stories.

Outlined below are some of the primary areas where CBD products have been proven to be beneficial:

- Pain relief and anti-inflammatory properties for arthritis and rheumatism
- Acne and skin conditions
- Mental disorders such as Autism, ADHD, Bipolar, Anorexia and Schizophrenia
- Addiction recovery
- Lou Gehrig's Disease (ALS)
- Anxiety, Depression and PTSD
- Neurological disorders such as Parkinson's, Alzheimer's Disease, Epilepsy Stroke, TMI's, MS and Fibromyalgia
- Cancer treatment for tumor growth inhibitors, increased appetite and pain relief
- Diabetes
- AIDS
- Digestive, Gastrointestinal and Endocrine Disorders such as IBS and Crohn's
- Sleep Disorders

Below we go into greater detail as to the specific ways that CBD impacts some of our most common ailments.

Cancer Treatment

The impetus behind creating NuLife CBD came from observing a family member's battle with terminal esophageal cancer in 2015 and how powerful and rapid a remedy CBD was during his final days. A mixture of CBD and THC supported him greatly in minimizing his pain and nausea and increasing his appetite. Using a variety of CBD products made his ultimate transition infinitely easier and less painful. Having an increased appetite and decreased nausea allowed him to maintain critical nutrition levels and keep weight on, which is important when dealing with the fallout from chemotherapy and radiation. Throughout the process of his cancer treatment, the CBD allowed him pain free nights where he was able to sleep, and in the end, it increased the overall quality of his life before passing.

According to the **National Cancer Institute**, "Cannabidiol (CBD)… may relieve pain and lower inflammation without causing the 'high' of delta-9-THC. Cannabinoids may be useful in treating the side effects of cancer and cancer treatment." CBD has also been seen as a growth inhibitor in tumors and may impact cellular dysplasia." [sic]

A Miracle Pain Remedy

Do a bit of internet research and you will discover a plethora of reviews and testimonials from people who have traded in their pharmaceutical-grade pain and anti-inflammatory medications for the all-natural benefits of CBD. CBD products are effective in treating both acute and chronic pain and can come in the form of CBD oil, CBD ointment and cannabis pain cream and gel for topical use, vaping CBD oil to be inhaled and CBD gummies, tinctures, capsules and powders to be ingested. 34-year-old Jen Barker from New Mexico had tried everything to minimize the pain she experienced each month during her menstrual cycle, often doubled over with abdominal cramping. She experienced immediate relief from her symptoms upon trying CBD capsules and after 3 months of daily usage her cycle became more manageable than ever before.

Treatment for Epilepsy and Seizures

13-year-old Emma Crozier of Arizona uses CBD to manage the epileptic seizures that have plagued her life since the age of 2. The use of high-grade Medical CBD has reduced the number of her grand mal seizures from multiple a day to one one [sic] or two per week. According to a **Consumer Reports** article, FDA-approved seizure medications "fail about one-third of all sufferers, either because the drugs don't stop the seizures or because the side effects are too severe." Epileptic seizures are caused by irregularly misfiring electrical charges within the brain, which can result in convulsions and altered or impaired states of consciousness. The specific cause of epilepsy remains unknown, but can sometimes be the result of traumatic brain or head injuries, hormonal issues or the introduction of a virus.

Treatment for Multiple Sclerosis

Multiple Sclerosis or MS is a chronic autoimmune disease that affects the central nervous system, optic nerves and brain and can be incredibly painful when patients suffer from frequent muscle spasms. CBD has been shown to reduce spasm levels and greatly lower the pain of MS side effects.

Neuroprotection Against Neurological Disorders

Extensive research is currently being conducted around the positive benefits of using CBD to treat a variety of neurological disorders that cause the degeneration of the brain and nerves over time. Patients with disorders such as Alzheimer's, Multiple Sclerosis (MS), Parkinson's disease, traumatic brain injuries and the negative effects of an ischemic attack such as a stroke have seen significant success in implementing CBD as part of their treatment plan based on its ability to reduce the inflammation that can make neurodegenerative symptoms worse.

Treatment of Depression and Other Mental Health Applications

Unlike THC, who's [sic] psychotropic effects can impact anxiety and paranoia levels, CBD has shown great promise in improved cognitive function and enhanced relief for patients suffering from a wide variety of mental disorders such as anxiety, depression, addiction, schizophrenia, bipolar disorder, OCD and PTSD.

Excerpt from www.nulifecbdoils.com/cbd-product-reviews

Reviews

Rated **5** out of 5
Adria *(verified owner)* – July 12, 2019
This cream is wonderful and has really helped my arthritis

 CBD Pain Cream – 1000mg CBD 2 Oz

Rated **5** out of 5
Peter Prinsen *(verified owner)* – June 24, 2019
I have arthritis in both feet and after using the 1000 mg product for a few days got significant relief from the pain. Orthotics has helped a little but nothing has helped as much as the cream.

 CBD Pain Cream – 1000mg CBD 2 Oz

Rated **5** out of 5
Anonymous *(verified owner)* – June 21, 2019
My blood pressure has always been high... now it is in the low normal range. Diet, Exercise–Same... Only difference is CBD.

 CBD Oil 500mg (30ml) Bottle

Excerpt from www.nulifecbdoils.com/what-is-cbd-hemp-oil-cannabidiol-information

The Most Common CBD Uses

* * *

The most common reasons that people use CBD are to provide natural pain relief and anti-inflammation for ailments that include the following:

- Joint pain from osteo and rheumatoid arthritis
- Support for neurodegenerative diseases such as alzheimers and parkinsons
- Treatment for PTSD, depression, anxiety, schizophrenia and other mental health considerations
- Support with chronic insomnia
- Support with quitting smoking and other substance use disorders
- Chronic pain from injuries
- Increased appetite, reduced nausea and pain relief for cancer patients
- Support for treatment-resistant epilepsy in both children and adults
- Support with autoimmunity for inflammatory and pain-associated disorders such as fibromyalgia and MS
- Preventative diabetes measure and effective treatment for existing Type 1

- External uses such as psoriasis and acne
- Antitumor cancer treatments for leukemia, cervical and colon cancers and combination therapy for breast and prostate cancer
- Treatment of antibiotic resistant bacteria

We strongly urge you to review all claims for your products, including consumer testimonials and product reviews, and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a federal district court injunction or an administrative cease and desist order. An order also may require that you refund money to consumers.

With regard to the advertising claims discussed above, please notify staff attorney Keith Fentonmiller via electronic mail at kfentonmiller@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC staff's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Fentonmiller at 202-326-2775.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 9, 2019

VIA FEDERAL EXPRESS
Brett Benning, CEO
Ocanna Co.
1002 E. University Dr. Ste. 101
Phoenix, AZ 85034

Dear Mr. Benning:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you may be making false or unsubstantiated advertising claims about the health benefits of products containing cannabidiol (CBD), a chemical compound derived from the cannabis plant.

Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, prohibit unfair or deceptive advertising. Specifically, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made. This substantiation requirement applies whether the advertiser disseminates such health claims directly via traditional advertising or indirectly via the use of a product name, website name, or metatags. This requirement also extends to consumer endorsements. It's not enough that an endorsement represents the consumer's honest opinion or experience. Reasonable consumers may interpret an endorsement claiming a health benefit from the use of a product as representing that the product is likely to be effective in achieving that benefit. Under FTC law, an advertiser must possess and rely on competent and reliable scientific evidence to support health claims, both express and implied, made through the use of endorsements.

FTC staff has reviewed your website, www.ocannacbd.com, for potential violations of the FTC Act. We are concerned that one or more of the health benefit claims excerpted below may not be substantiated by competent and reliable scientific evidence.

Excerpts from www.ocannacbd.com/product/gummies

OCANNA CBD GUMMIES

Delicious and highly effective, our CBD infused gummies...

BENEFITS

- Fights inflammation – the root cause of most major degenerative diseases, including arthritis, heart disease, fibromyalgia, cancer, asthma, and a wide spectrum of autoimmune disorders. May also aid with... epileptic seizures and anxiety disorders.

* * *

Related products

Cream
Ocanna's organic CBD Cream is formulated with... CBD extract that reduces inflammation, providing... arthritis pain relief....

* * *

Oil
Ocanna CBD Oil is a natural dietary supplement that may be effective in the fight against... depression, PTSD, ... and epilepsy, in addition to a broad spectrum of inflammatory diseases including heart disease, arthritis, fibromyalgia, [and] asthma....

* * *

Excerpts from www.ocannacbd.com/cbd-hope-for-digestive-distress

CBD – Hope for Digestive Distress

* * *

The study of CBD's (cannabinoids) and their potential curative affects [sic] on gut health and the issues directly relating to it, should be considered one of the more exciting aspects of this amazing curative. For anyone suffering with the activity-limiting issues of digestive distress, be it Crohns, IBS, ulcers, GERD, Leaky Gut and more, the potential to ease or alleviate their symptoms goes well beyond heartening.... [C]hronic digestive ailments such as Crohns disease have been experimentally treated with promising results using CBD. Crohns disease is the result of ulcers and lacerations within the stomach and small intestines that remain untreated for a prolonged duration. The soothing anti-inflammatory properties of CBD are invaluable for such disorders.

Excerpts from www.ocannacbd.com/cbd-a-potent-therapy-for-fibromyalgia

CBD – A Potent Therapy For Fibromyalgia

* * *

[U]sing a plant-based product like CBD oils and cream to reduce both fibromyalgia pain and inflammation... can be an excellent alternative.

* * *

Excerpts from www.ocannacbd.com/promising-affects-of-cbd-on-arthritis-pain

Promising Affects [sic] of CBD on Arthritis Pain

* * *

CBD- A Potent Therapy For Arthritis

CBD is best known for its analgesic properties (pain relief), anti-inflammatory abilities (reducing swelling and the localized burning sensation), along with antibacterial properties. This makes it very effective in mitigating the most common symptoms of arthritis.

CBD products can ease or eliminate arthritic symptoms....

* * *

For those suffering from the excruciating pain of arthritis, CBD is a precious, plant-based gift.

In 2008, a review related to research on CBD and its ability to manage pain foretold the possibility of CBD becoming a potent formulation in the near future. With every new study and report, we see more scientific evidence surfacing that shows how and why CBD is effective in treating arthritis

Excerpts from www.ocannacbd.com/testimonials-supporting-cbd-and-wellness

I have good news. It DOES work

Just wanted to give a review update on my newfound journey with Ocanna CBD. I think it's been a good 2 weeks or so that I've been on this CBD oil, and I have some good news. It DOES work. I utilize this amazing oil for my panic/anxiety attacks. I woke up yesterday and realized I hadn't had any in a little while, then stopped and attributed it to this bottle of goodness. If CBD can help so many people to either get off of meds or lessen the use of them, let's utilize it more. It

has piqued my curiosity so much so that I will be trying out the Chews maybe next month. Thanks Team Ocanna!
–Shan Apr 12, 2018

My patients with Autism
Yes!!! I am recommending it after trying it myself to my patients with Autism. The topical is my favorite because can put on the bottoms of their feet or up their backs and can start with just a small amount to be sure they tolerate it well. Then can go up. Once they have used the topical, then go to the oil. We are starting slowly with 1-2 drops then working up. Have 2 kids on it, both are 4 years old and so far so good! Parents are happy they are sleeping through the night!
– Windy Jun 19, 2018

Osteoarthritis
I'm a retired Marine, after spending 20 years in uniform, romping and stomping all over the globe. Unfortunately, it left me with osteoarthritis in all of my main joints. I was maxing out my pain meds and didn't want to have to get doped up with strong narcotics, so I needed to do something. After taking CBD oil for 2 weeks I noticed a difference and after 2 months I've been able to cut my pain meds in half. As I continue to adjust the dosage of CBD, I'm hoping to cut back further on the pain meds or get off them completely.
– Michael Nov 05, 2018

Arthritis Relief At Last!
Severe arthritis pain is an unwelcome companion in my life. Both hands and feet are so bad with rheumatoid arthritis that I've got fused joints in both. It's the bone-on-bone pain in my right hip and knee that really slowed me down though. I could hardly go anywhere because moving hurt so much. And at night – there was no quality sleep because of excruciating pain. Nothing seemed to cut the pain or give me any real relief.
Then my daughter sent me Ocanna 300mg CBD cream hoping it might work. I was amazed at what a difference it made. In just a few days, I was able to walk throughout two stores alongside my husband, and never had to stop or slow down. Better yet, I'm sleeping without fighting constant pain, even when I accidentally roll onto my right side.
I admit to hesitating about using a cannabis-based product (that's just how my generation views this stuff), but now that I've experienced how effective it really is, I'll never hesitate again. I'm an 85-year old believer in the power of Ocanna and their CBD cream!
– Barbara March 18, 2019

We strongly urge you to review all claims for your products, including consumer testimonials, and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a federal district court injunction or an administrative cease and desist order. An order also may require that you refund money to consumers.

With regard to the advertising claims discussed above, please notify staff attorney Keith Fentonmiller via electronic mail at kfentonmiller@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC staff's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Fentonmiller at 202-326-2775.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices

U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

March 28, 2019

Young J. Lee, MD, President
Advanced Spine and Pain, LLC (d/b/a Relievus)
813 East Gate Dr. Suite B
Mount Laurel, NJ 08054-1238

RE: 565256

Dear Dr. Young J. Lee:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the internet address www.relievuscbdoil.com in February 2019 and has determined that you take orders there for the products "CBD Salve," "CBD Oil" (in 5 different flavors), and "CBD for Dogs," which you promote as products containing cannabidiol (CBD). We have also reviewed your website at the internet address www.relievus.com, and your social media websites at www.facebook.com/Relievus/ and https://twitter.com/Relievus; these websites direct consumers to your website, www.relievuscbdoil.com, to purchase your products. FDA has determined that your "CBD Salve" and "CBD Oil" products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). FDA has also determined that your "CBD for Dogs" product is an unapproved new animal drug that is unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission (FTC) has reviewed your website for potential violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. 45(a) and 52.

Unapproved New and Misbranded Human Drug Products

Based on our review of your websites, your "CBD Salve" and "CBD Oil" products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body.

Your "CBD Oil" products are not labeled as dietary supplements, but we note that the directions for use begin with the phrase "[a]s a hemp supplement…." Based on this language, it appears you may intend to market your product as a dietary supplement. However, it cannot be a dietary supplement, because it does not meet the definition of a dietary supplement under sections 201(ff)(3)(B)(i), 201(ff)(3)(B)(ii), and 201(ff)(2)(A)(i) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i), 321(ff)(3)(B)(ii), and 321(ff)(2)(A)(i).

FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act. Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, 21 U.S.C. 355, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.[1] FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.

Furthermore, your product labeling states that your "CBD Oil" products are intended to be taken sublingually. The FD&C Act defines the term "dietary supplement" in section 201(ff)(2)(A)(i) of the FD&C Act, 21 U.S.C. 321(ff)(2)(A)(i), as a product that is "intended for ingestion." Because sublingual products are intended to enter the body directly through the skin or mucosal tissues, they are not intended for ingestion. Therefore, this is an additional reason why your "CBD Oil" products do not meet the definition of a dietary supplement under the FD&C Act.

Moreover, your "CBD Oil" product label has a nutrition facts panel. To the extent that your "CBD Oil" product label suggests that it is a food, you should be aware that it is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), to introduce or

[1] CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain and GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome). FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations [21 CFR 312.2], unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

deliver for introduction into interstate commerce any food to which has been added a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless the drug was marketed in food before any substantial clinical investigations involving the drug were instituted. The existence of substantial clinical investigations regarding CBD has been made public. Based on available evidence, FDA has concluded that section 301(ll) prohibits the introduction into interstate commerce of any food to which CBD has been added.

Examples of claims observed on your websites and social media websites that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your website www.relievuscbdoil.com: Webpage titled – "Home"

- "We carry cannabinoid oil and CBD salve for treating your conditions. If you have any of the indications listed below, please consider trying our cannabis treatment products! . . . Anxiety . . . Chronic Inflammation . . . Cancer Pain . . . Depression . . . Chronic Pain . . ."

On your website www.relievuscbdoil.com: Webpage titled – "Indications"

- "Here you can find a list of indications that we can treat with our hemp oil products . . . Anxiety . . . Chronic Inflammation . . . Cancer Pain . . . Depression . . . Chronic Pain . . ."
- "Other indications . . . Alzheimer's disease . . . Amyotrophic Lateral Sclerosis (ALS) . . . Anxiety . . . Autoimmune Disorders . . . Cancer . . . Chronic inflammation . . . Chronic Pain . . . Crohn's Disease . . . Depression . . . Diabetes . . . Inflammatory Bowel Disease . . . Obsessive compulsive disorder (OCD) . . . Panic disorder . . . Parkinson's disease . . . Post-traumatic stress disorder (PTSD) . . . Rheumatoid arthritis . . . Schizophrenia . . . Substance Use Disorders"

On your website www.relievuscbdoil.com: Webpage titled – "Health Benefits"

- "CBD successfully stopped cancer cells in multiple different cervical cancer varieties."
- "CBD also decreased human glioma cell growth and invasion, thus suggesting a possible role of CBD as an antitumor agent."
- "CBD may also protect brain cells from beta-amyloid toxicity, making it a potential therapeutic agent in Alzheimer's and Parkinson's disease."
- "CBD, due to its anti-inflammatory and antioxidant properties, may be a promising agent to treat and prolong survival in Amyotrophic Lateral Sclerosis (ALS) patients."
- "CBD is a potential treatment for psychosis."
- "CBD improves the symptoms of schizophrenia."
- "Cannabidiol May Treat Depression"
- "Researchers suggest that it may be effective for panic disorder, obsessive compulsive disorder and post-traumatic stress disorder"
- "Studies suggest that cannabinoids may be a new class of drugs for the treatment of chronic pain."

- "Cannabidiol May Provide Treatment for Alzheimer's disease"
- "Due to its anti-inflammatory effect, cannabinoids may provide relief of joint pain and swelling, and decrease joint destruction and disease progression."
- "CBD . . . can possibly be used as a therapeutic agent for treatment of type 1 diabetes at an early stage of the disease."
- "Cannabidiol May Help with Inflammatory Bowel Disease"
- "Cannabidiol May be Effective for Treating Substance Use Disorders"
- "CBD reduced the rewarding effects of morphine and reduced drug seeking of heroin"
- "CBD may be a promising substance for people who abuse opioids."
- "CBD may be used to avoid or reduce withdrawal symptoms."

On your website www.relievus.com: Webpage titled – "Common Pain Conditions and Symptoms"

- "CBD Hemp Oil for Pain . . . It can also aid in the treatment of . . . depression, reduce anxiety, and relieve chronic pain and inflammation."
- "Here is a list of indications that CBD oil can help . . . Alzheimer's disease . . . Amyotrophic Lateral Sclerosis (ALS) . . . Anxiety . . . Autoimmune Disorders . . . Cancer . . . Chronic inflammation . . . Chronic Pain . . . Crohn's Disease . . . Depression . . . Diabetes . . . Inflammatory Bowel Disease . . . Obsessive compulsive disorder (OCD) . . . Panic disorder . . . Parkinson's disease . . . Post-traumatic stress disorder (PTSD) . . . Rheumatoid arthritis . . . Schizophrenia . . . Substance Use Disorders"

On your Facebook (www.facebook.com/Relievus/) and Twitter (https://twitter.com/Relievus) websites:

- September 14, 2018 post – "Cannabidiol Fights Against Cancer CBD and other chemicals found in Cannabis have an anti tumor effect and could be used to improve standard treatments. Please visit our website for more information! Relievuscbdoil.com. #cbd #cannabiscommunity #cannaboid . . . #relievus #pain"

Your "CBD Salve" and "CBD Oil" products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Your "CBD Salve" and "CBD Oil" products are also misbranded within the meaning of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that their labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended, 21 CFR 201.5. Your "CBD Salve" and "CBD Oil" products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. FDA-approved

prescription drugs which bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson, however, your products are not exempt from the requirement that their labeling bear adequate directions for use, 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Unapproved New Animal Drug

Based on our review of your websites, your "CBD for Dogs" product is a drug under section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals.

Examples of claims observed on your website that show the intended uses of your "CBD for Dogs" product include, but may not be limited to, the following:

On your website www.relievuscbdoil.com: Webpage titled – "Indications"

- "Here you can find a list of indications that we can treat with our hemp oil products . . . Anxiety . . . Chronic Inflammation . . . Cancer Pain . . . Chronic Pain . . ."

On your website www.relievuscbdoil.com: Webpage titled – "Health Benefits"

"Cannabidiol Fights Against Cancer
- CBD and other chemicals found in Cannabis have an antitumor effect and could be used to improve standard treatments.
- CBD successfully stopped cancer cells in multiple different cervical cancer varieties.
- CBD decreased the ability of the cancer cells to produce energy, leading to their death.
- CBD treatment helps lymphokine-activated killer (LAK) cells kill cancer cells better.
- CBD increased tumor cell death in leukemia and colon cancer."

"Cannabidiol Relieves Pain
…
- CBD significantly decreased chronic inflammatory and neuropathic pain.
- Cannabidiol shows promising results for the treatment of postoperative pain, chronic pain associated with . . . cancer, rheumatoid arthritis and neuropathic pain."

"Cannabidiol May Be Beneficial in Rheumatoid Arthritis
- Due to its anti-inflammatory effect, cannabinoids may provide relief of joint pain and swelling, and decrease joint destruction and disease progression.
- Administration of CBD protected joints against severe damage, decreased

progression and produced improvement of arthritis in animal models."

Because your "CBD for Dogs" product is intended to cure, mitigate, treat, or prevent disease in animals, it is a drug within the meaning of section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B). Moreover, this product is a new animal drug, as defined by section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because it is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. It is not the subject of an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act, 21 U.S.C. 360b, 360ccc, and 360ccc-1. Therefore, this product is unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). The introduction or delivery for introduction into interstate commerce of this adulterated drug violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Unsubstantiated Advertising Claims

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See POM Wonderful LLC v. FTC, 777 F.3d 478, 504-05 (D.C. Cir. 2015); FTC v. Direct Mktg. Concepts, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), aff'd, 624 F.3d 1 (1st Cir. 2010); FTC v. Nat'l Urological Group, Inc., 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), aff'd, 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75, 866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See Daniel Chapter One, FTC Dkt. No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), aff'd, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by competent and reliable scientific evidence. The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal

action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers.

With regard to the advertising claims discussed above, please notify Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

With regard to the FDA-related violations described in this letter, please notify FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, 10903 New Hampshire Avenue, WO51, Silver Spring, MD 20993-0002 or by email to FDAADVISORY@fda.hhs.gov.

Sincerely,

Donald D. Ashley -A

Digitally signed by Donald D. Ashley -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -A
Date: 2019.03.28 17:23:49 -04'00'

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

MARY ENGLE

Digitally signed by MARY ENGLE
Date: 2019.03.28 10:45:28 -04'00'

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

cc:
Relievus
904 Chicago Drive
Jenison, MI 49428

U.S. FOOD & DRUG ADMINISTRATION

FTC

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

March 28, 2019

PotNetwork Holdings, Inc.
Attn: Mr. Gary Blum, President
3531 Griffin Road
Fort Lauderdale, FL 33312

RE: 564030

Dear Mr. Blum:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the internet address www.diamondcbd.com in September 2018 and has determined that you take orders there for various products you claim to contain cannabidiol (CBD), including "Liquid Gold Gummies (Sweet Mix)," "Liquid Gold Gummies (Sour Mix)" and "blue CBD Crystals Isolate 1500mg." The claims on your website establish that these products are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission has reviewed your website for potential violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Examples of some of the claims observed on your website that provide evidence that your products are intended for use as drugs include the following:

On the webpage titled "WHAT IS CBD?":

- "A 2015 study found that CBD may be neuprotective [*sic*] in adult and neonatal ischemia, brain trauma, Alzheimer's disease, Parkinson's disease, Huntington's chorea, and amyotrophic lateral sclerosis (Lou Gehrig's disease)."

- "CBD was administered after onset of clinical symptoms, and in both models of arthritis the treatment effectively blocked progression of arthritis."

- "Natural cannabinoids, such as CBD (cannabidiol), have been shown in research

to have therapeutic possibilities in helping diabetes."

On the webpage titled "A History Of The Power of Organic CBD Hemp Oil Benefits (Part II)":

- "And there have been scores of research studies into CBD's effects on a myriad of conditions from epilepsy to Alzheimer's, autism, PTSD, and much more."

On the webpage titled "CBD in the Treatment of Cancer":

- "A variety of studies carried out in the past few years have shown that cannabinoids found in hemp possess anti-proliferative and pro-apoptotic (tumor killing) effects, creating an abundance of evidence to support the use of CBD as an anti-cancer agent."

- "Experiments carried out on both human cells and on animals have shown that phytocannabinoids (cannabinoids found in hemp which act like human endocannabinoids) can lead to inhibition of the growth of many tumor types including brain cancer, breast cancer, colon cancer, lung cancer, skin cancer, and even leukemia. Many of these studies show CBD's ability to disrupt cancer cell migration, preventing its spread."

- "Interestingly, however, in some lab studies, CBD has also shown the ability to kill cancer cells directly without the help of our immune system."

On the webpage titled "CBD Shows Potential in Treating Alzheimer's Disease":

- "CBD has been shown to possess neuroprotective, anti-inflammatory, and antioxidant properties in the lab. These properties suggest that the compound could be therapeutically beneficial for reducing or even inhibiting the cognitive and functional impairment that occurs with Alzheimer's disease. Finds also indicate that CBD promotes neurogenesis, or the growth and development of neurons, slowing the deterioration of cognitive functions."

- Alzheimer's is a serious and life-threatening disease that requires professional medical attention. But these and other studies show that a lot can be done just by tapping into the health benefits program offered by Mother Nature. Try our line of CBD Oils."

Your products "Liquid Gold Gummies (Sweet Mix)," "Liquid Gold Gummies (Sour Mix)" and "blue CBD Crystals Isolate 1500mg," are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products "Liquid Gold Gummies (Sweet Mix)," "Liquid Gold Gummies (Sour Mix)" and "blue CBD Crystals Isolate 1500mg," are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your products "Liquid Gold Gummies (Sweet Mix)," "Liquid Gold Gummies (Sour Mix)" and "blue CBD Crystals Isolate 1500mg," fail to bear adequate directions for their intended uses and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

We also note that your "blue CBD Crystals Isolate 1500mg" product is labeled with the phrase "nutritional supplement." To the extent that you intend to market this product as a dietary supplement, you should be aware that FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(i) and (ii)]. Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, 21 U.S.C. § 355, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.

CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex.[1] FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR § 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the Act. FDA is not

[1] See "Sativex Commences US Phase II/III Clinical Trial in Cancer Pain," available at https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain and "GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome," available at https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial.

aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the Act, but you may present FDA with any evidence that has bearing on this issue.

Similarly, we note that your "Liquid Gold Gummies (Sweet Mix)" and "Liquid Gold Gummies (Sour Mix)" products contain a Nutrition Facts panel. To the extent that you intend to market these products as foods, you should be aware that it is a prohibited act under section 301(ll) of the Act (21 U.S.C. 331(ll)) to introduce or deliver for introduction into interstate commerce any food to which has been added a drug approved under section 505 of the Act or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless the drug was marketed in food before any substantial clinical investigations involving the drug were instituted. CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. Based on available evidence, FDA has concluded that section 301(ll) prohibits the introduction into interstate commerce of any food to which CBD has been added.

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

Unsubstantiated Advertising Claims

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See POM Wonderful LLC v. FTC, 777 F.3d 478, 504-05 (D.C. Cir. 2015); FTC v. Direct Mktg. Concepts, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), aff'd, 624 F.3d 1 (1st Cir. 2010); FTC v. Nat'l Urological Group, Inc., 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), aff'd, 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75, 866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See Daniel Chapter One, FTC Dkt. No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), aff'd, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by competent and reliable scientific evidence. The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers.

With regard to the advertising claims discussed above, please notify Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

FD&C Act Violations

With regard to the FDA-related violations, you should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Shawn Goldman, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Mr. Goldman at Shawn.Goldman@fda.hhs.gov.

Sincerely,

William A. Correll Jr.
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
US Food and Drug Administration

MARY ENGLE

Digitally signed by MARY ENGLE
Date: 2019.03.28 10:39:28 -04'00'

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

cc:
Dr. Richard E. Goulding
CEO, PotNetwork Holdings, Inc.
3531 Griffin Road
Fort Lauderdale, FL 33312

Kevin Hagen
President, First Capital Venture Co.
3531 Griffin Road
Suite #100
Fort Lauderdale, FL 33312

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

March 28, 2019

CJ Montgomery
Nutra Pure LLC
500 Broadway Street, Suite 480
Vancouver, WA 98660

RE: 567714

Dear Mr. Montgomery:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the internet address https://www.cbdpure.com/ in February 2019 and has determined that you take orders there for the products "Hemp Oil" (100mg, 300mg, and 600mg) and "CBD Softgels" which you promote as products containing cannabidiol (CBD). The claims on your website establish that the products are drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission (FTC) has reviewed your website for potential violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. 45(a) and 52.

Although you market "Hemp Oil" and "CBD Softgels" as dietary supplements, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i) and (ii). Under those provisions, if an article (such as CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, 21 U.S.C. 355, or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance

are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.

CBD is the active ingredient in the approved drug product Epidiolex. Furthermore, the existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex[1]. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations, 21 CFR 312.2, unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the Act. FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.

Examples of claims observed on your website https://www.cbdpure.com/ that establish the intended use of your products as drugs include, but may not be limited to, the following:

On the webpage titled "CBD: Alzheimer's":

- "For Alzheimer's patients, CBD is one treatment option that is slowing the progression of that disease."

- "Science also shows that CBD has anti-emetic, anti-convulsive, anti-inflammatory and analgesic properties. Because all of these come into play with Alzheimer's, particularly brain inflammation, CBD is a viable option for minimizing these effects within the brain."

On a webpage titled "CBD: Anxiety":

- "Cannabidiol (CBD) Treats Neuropsychiatric Disorders"

- "…evidence that the therapeutic efficacy of CBD in the treatment of anxiety-related disorders was pronounced, particularly in the areas of conditioned fear responses, stress, generalized anxiety disorder, social phobia, panic disorder, PTSD, and OCD.

---

[1] See "Sativex Commences US Phase II/III Clinical Trial in Cancer Pain," available at https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain and "GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome," available at http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda.

- "CBD can be effective as a treatment in and of itself, or in combination with other treatments."

On the webpage titled "CBD: Depression":

- "For many, CBD holds the answers to treating depression."

- "CBD is a very broad treatment options that targets multiple symptoms and ranges present with depression." [*sic*]

On the webpage titled "CBD: Fibromyalgia":

- "Fibromyalgia is conceived as a central sensitization state with secondary hyperalgesia. CBD has demonstrated the ability to block spinal, peripheral and gastrointestinal mechanisms responsible for the pain associated with migraines, fibromyalgia, IBS and other related disorders."

On the webpage titled "CBD: Skin Conditions":

- "The compounds present in CBD are found to have anti-inflammatory effects . . . Psoriasis is an inflammatory disease"

- "In the study referenced here, CBD was tested specifically in the treatment of psoriasis and found be effective in both stopping the spread of the disease and in alleviating symptoms."

- "…CBD provides a safe, long term option for those suffering from skin disorders."

On your webpage titled "CBD: Inflammation":

- "'Chronic inflammation' [is] when the body is unable to shut off the inflammatory response. This category of inflammation encompasses the following disorders: Rheumatoid arthritis, Psoriatic arthritis, Chron's disease and other inflammatory bowel diseases, Fibromyalgia, Atherosclerosis, Grave's disease, Diabetes, Lupus, Celiac disease . . ."

- "Cannabidiol (CBD) . . . is building a reputation as an effective and safe treatment alternative in the battle against chronic inflammation."

The claims on your websites establish that the products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body.

Your products “Hemp Oil” and “CBD Softgels” are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are “new drugs” under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended, 21 CFR 201.5. Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, 21 U.S.C. 353(b)(1)(A), can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products “Hemp Oil” and “CBD Softgels” are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, “Hemp Oil” and “CBD Softgels” fail to bear adequate directions for their intended uses and, therefore, the products are misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Unsubstantiated Advertising Claims

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See POM Wonderful LLC v. FTC, 777 F.3d 478, 504-05 (D.C. Cir. 2015); FTC v. Direct Mktg. Concepts, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), aff’d, 624 F.3d 1 (1st Cir. 2010); FTC v. Nat’l Urological Group, Inc., 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), aff’d, 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. Natural Solution, Inc., No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75, 866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name,

metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See Daniel Chapter One, FTC Dkt. No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), aff'd, 405 Fed. Appx. 505 (D.C. Cir. 2010).

The FTC is concerned that one or more of the efficacy claims cited above may not be substantiated by competent and reliable scientific evidence. The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers.

With regard to the advertising claims discussed above, please notify Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

With regard to the FDA-related violations described in this letter, please notify FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance, 10903 New Hampshire Avenue, WO51, Silver Spring, MD 20993-0002 or by email to FDAADVISORY@fda.hhs.gov.

Sincerely,

Donald D. Ashley -A

Digitally signed by Donald D. Ashley -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -A
Date: 2019.03.28 17:22:07 -04'00'

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

MARY ENGLE

Digitally signed by MARY ENGLE
Date: 2019.03.28 10:41:10 -04'00'

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

From: Nutra Pure
Sent: 29 Mar 2019 18:42:59 -0700
To: Cleland, Richard L.
Cc: fdaadvisory@fda.hhs.gov
Subject: Re: #567714 Letter
Attachments: 567714_Prelim_Response.pdf

Mr. Cleland,

Please find attached the response to Mr. Ashley's warning letter received this morning. We look forward to working to resolve the pending issues.

Sincerely,
CJ Montgomery
President - Nutra Pure LLC

March 29th, 2019

Donald D. Ashley
U.S Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Mr. Ashley,

I am in receipt of your letter (Re: **567714**) as of this morning, dated yesterday. Rest assured that we take compliance very seriously, and this has my full attention. As a licensed attorney with fourteen years' experience in the dietary supplements industry, I know well the high and evolving standards expected in the marketing of any dietary supplement, and in particular hemp-related supplements in light of the recent passage of 218 U.S. Farm Bill. I pledge to take all necessary proactive steps to ensure the marketing of CBDPure meets the highest standard, and have already taken steps to remove and change certain language found on the CBDPure website accordingly.

As your review no doubt noted, the language and quotes in question are not from our marketing or sales pages, but rather from internal "Resources" pages, and not public-facing e-commerce pages. On each one, we have taken pains to ensure that we reference only peer-reviewed studies and standards that are generally accepted by the scientific community, and do not rely on any self-serving industry studies that are not subject to the same rigorous standards as the National Institute of Health, or the Journal of American Medicine. We have deliberately tried to ensure that no quotes from these studies are taken out of context, nor any marketing claims made that these studies reflect our brand specifically, but may have fallen short in some areas. Nevertheless, we take full responsibility for all content on our website, and have made further revisions and redactions to ensure that no visitor would have a risk of confusion about any potential structure/function claims not permissible in the marketing of dietary supplements.

With regards to the CBD: Alzheimer's page referenced in your warning letter, this page was not linked from any pages of the website where laypeople could access it. The quotes on that page are taken directly from the studies cited, and the footnote citations are to the government websites where they are currently published. However, I agree that the word "treatment" in two of the quoted sentences is not permissible, and given that this is a recognized disease for which it would be difficult to provide a suitable level of disclosure to educate a layperson seeking treatment options for a serious disease, we have removed all article language and quotes taken from the studies. We have left simple citations to the National Institute of Health, and the U.S. National Library of Medicine. Likewise, seeing no way to adequately modify the language on the page related to Fibromyalgia, we have removed all text from that page and left only the citations to studies listed on public government websites for consumers.

On the Inflammation and Skin Conditions pages, it is our position that, while related to human health and well-being, the content on the whole does not pertain specifically to diseases and or specific health conditions, or reference any impermissible structure/function claims. In three instances, the words "treat" or "treatment" were present, and have now been promptly removed. Likewise, any recognized disease in lists on the page or resources these pages link to have also been removed (e.g. Lupus). We have kept the footnotes listing the full study titles and publication link on governmental websites. No sales or marketing language will be used on any of these pages, now or in the future.

All of the above-discussed modifications have already been made, and we will make any other changes or qualification language deemed necessary or advised by your office in order to meet the highest standards. We have also begun a comprehensive review of all marketing materials, online and offline, provided or modified by our outside vendors of marketing services to ensure the highest level of compliance and transparency in all customer-facing mentions of our brand. While that review is still ongoing, it will be completed by April 8th, 2019.

Sincerely,

CJ Montgomery
President – Nutra Pure LLC

VENABLE LLP

600 MASSACHUSETTS AVE., NW WASHINGTON, DC 20001
T 202.344.4000 F 202.344.8300 www.Venable.com

Todd A. Harrison
T 202.344.4724
F 202.344.8300
TAHarrison@Venable.com

April 30, 2019

Via Federal Express
and email: Shawn.Goldman@fda.hhs.gov

Mr. Shawn Goldman
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Enforcement
Office of Compliance (HFS-608)
5001 Campus Drive
College Park, MD 20740-3835

Re: PotNetwork Holdings, Inc., Warning Letter #564030

Dear Mr. Goldman:

This letter responds to the above-referenced Warning Letter received by our client, PotNetwork Holdings ("the Company") on March 28, 2019. In the Warning Letter, the Agency alleges that the Company, through its website www.diamondcbd.com, makes certain impermissible disease claims regarding its hemp-derived cannabidiol ("CBD") dietary supplement products. As discussed in greater detail below, the Company used publications that reference disease states in a way that was compliant with the "third-party literature" exemption from labeling that was established by § 403B of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Despite compliance with this regulatory exception, the Company agrees to discontinue all references to disease states on its website and other marketing materials.

The Warning Letter also states that, pursuant to §§ 201(ff) and 301(ll) of the FDCA, CBD cannot lawfully be marketed as an ingredient in a dietary supplement or food because CBD is an FDA-approved drug and the subject of substantial clinical investigations as a drug. We respectfully disagree with the Agency's conclusion because the CBD used in the Company's products is not the same "article" as the CBD subject to investigation or approved as a drug. And, even if the "article" were the same, the exclusions from dietary supplements and food would not apply because CBD was marketed as a dietary supplement and food prior to the initiation of any substantial clinical trials. Relatedly, a New Dietary Ingredient ("NDI") notification is not required for the CBD in the Company's products because CBD was both marketed prior to October 15, 1994 and has been used as an article in the food supply in a chemically unaltered form. With that said, given the Agency's decision to hold a public hearing on the regulatory status of hemp and hemp-derived products, as well as its decision to open a docket and accept comments until July 2nd on this issue, we will address the regulatory status of CBD and submit evidence in support of the

lawfulness of CBD in food and dietary supplements to docket number FDA-2019-N-1482. However, we will copy you on our comments to the docket.

The company expects to fully implement the revisions identified in this response within the next 30 days. In the meantime, the company has fully addressed the specific statements referenced in the Warning Letter and is committed to not making any disease-related claims for its products.

DISCUSSION

The Warning Letter alleges that hemp-derived CBD products marketed by our client are intended to be used as drugs as a result of claims made on the product labeling and that the products are adulterated because, according to the Agency, CBD is not a permitted dietary or food ingredient or under FDA regulations. As previously stated, we will address the regulatory status of CBD in comments to the public docket.

As the Agency is aware, the Company markets hemp-derived CBD dietary supplements intended to support the body's endocannabinoid system and other normal structures and functions of the body. Such intended use falls firmly within the FDCA's permitted uses for dietary supplements. In the Warning Letter, however, the Agency cited numerous statements on the Company's website that mention various disease states. The Warning Letter alleges that such statements are claims that result in the products being unapproved drugs under § 201(p) of the FDCA. The Company understands that dietary supplement labeling may not reference disease states absent FDA approval of a health claim or otherwise make claims suggesting intended use as a drug product; however, the Company respectfully disagrees with the Agency's position that the statements on the website were part of the products' labeling. Specifically, § 403B of the FDCA provides that "a publication, including an article, chapter in a book, or an official abstract of a peer-reviewed scientific publication...shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers" when certain conditions are satisfied. The relevant conditions required for marketers to benefit from this exception require the publication to: (1) not be false and misleading; (2) not promote a particular brand or manufacturer of supplements; (3) be displayed or presented so as to present a balanced view of available scientific information; and (4) be displayed separate from the dietary supplements. *See* FDCA § 403B(a)(1)-(5). As cited in the Warning Letter, the Company's references to disease states were not on the individual product pages. Rather, the statements were made on webpages removed from product advertising that were dedicated to publications related to CBD history and research. In addition to being removed from the actual products on the website, the publications referencing disease states were not false and misleading, did not promote the Company's products or any other specific brand of CBD products, and were presented with items on the same subject—consequently, the publications met the criteria for the labeling exception under § 403B, and references to disease states by the publications were not prohibited.

Notwithstanding that the Company's use of publications referencing disease states was compliant with the requirements of § 403B of the FDCA, the Company will remove all statements from the website that reference disease states and conditions, including those statements enumerated in the Warning Letter. The Company is also undergoing a thorough review of all of its content to ensure that it complies with the FDCA and the Federal Trade Commission Act and anticipates that the revisions to the website, which are already underway, will be completed within days.

CONCLUSION

PotNetwork Holdings takes the Agency's concerns regarding the Company's website and products seriously, and in response to the Warning Letter, the Company is also undergoing an extensive review of its marketing materials and will comply with the Agency's request not to make disease and disease-related claims. As of the date of this letter, the Company has ceased making any disease-related claims referenced in the Warning Letter. The more extensive overhaul of its website and marketing materials will take place over the next 30 days. If the Agency still has concerns, the Company respectfully requests a meeting with the Agency.

Best regards,

Todd A. Harrison
Counsel to PotNetwork Holdings

cc: William Correll, Director, Office of Compliance, CFSAN, FDA
Rich Cleland, Federal Trade Commission
PotNetwork Holdings, Inc.

Relievus™

April 3, 2019

U.S. Food and Drug Administration
CDER/OC/Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
W051
Silver Spring, MD 20993-0002
Attn: Donald D. Ashley

RE: 565256

Dear Mr. Ashley:

We are in receipt of your letter, dated March 28, 2019, with regards to our promotion of Relievus CBD-related products.

While we may disagree with some of your assertions and conclusions, we respectfully will remove all CBD products and promotions from our website and all social media platforms immediately. We will discontinue the sale of all CBD-related products until we receive further guidance from the FDA.

Any patient who inquiries about purchasing additional CBD products from us will be notified that we have discontinued the sale of such products until we receive further guidance from the FDA.

If you require any additional information from us, please contact me by mail at Relievus, 813 East Gate Drive, Suite B, Mt. Laurel, NJ 08054 or call me directly at 609-870-2300.

Regards,

Ronald Saltiel
Chief Operating Officer

VENABLE LLP

ROCKEFELLER CENTER
1270 AVENUE OF THE AMERICAS
24TH FLOOR
NEW YORK, NY 10020
T 212.307.5500 F 212.307.5598 www.Venable.com

Leonard L. Gordon
T 212-370-6252
llgordon@venable.com

May 8, 2019

VIA E-MAIL (RCLELAND@FTC.GOV.

Richard Cleland
Assistant Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Rich:

Todd Harrison and I represent PotNetwork Holdings, Inc. ("PNI") regarding the March 28, 2019, warning letter that the FDA and FTC sent to PNI. We responded to the FDA on May 1, 2019, and you were copied on same. A copy is attached. Pursuant to our emails of April 12, 2019, we respond today to the FTC regarding the FTC issues raised in the Warning Letter.

The Warning Letter identified disease claims made for some of PNI's CBD products and raised concerns that those claims were unsubstantiated and potentially violative of the FTC Act.

PNI takes the FDA and FTC's concerns seriously, and PNI has removed all of the identified claims, as well as similar claims, from its website. As discussed in the May1, 2019 letter to the FDA, PNI is undergoing an extensive review and overhaul of all of its marketing materials to address any other FTC-related issues.

If you have additional concerns, please let us know.

Very truly yours,

Leonard L. Gordon

cc: Todd Harrison

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Mary K. Engle
Associate Director

September 17, 2019

VIA FEDERAL EXPRESS
Brad Keller
NuLife CBD Oils, LLC
3312 Independence Way
King of Prussia, PA 19434

Dear Mr. Keller:

The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you may be making false or unsubstantiated advertising claims about the health benefits of products containing cannabidiol (CBD), a chemical compound derived from the cannabis plant..

Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, prohibit unfair or deceptive advertising. Specifically, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made. This substantiation requirement applies whether the advertiser disseminates such health claims directly via traditional advertising or indirectly via the use of a product name, website name, or metatags. This requirement also extends to consumer endorsements. It's not enough that an endorsement represents the consumer's honest opinion or experience. Reasonable consumers may interpret an endorsement claiming a health benefit from the use of a product as representing that the product is likely to be effective in achieving that benefit. Under FTC law, an advertiser must possess and rely on competent and reliable scientific evidence to support health claims, both express and implied, made through the use of endorsements.

FTC staff has reviewed your website, www.nulifecbdoils.com, for potential violations of the FTC Act. We are concerned that one or more of the health benefit claims excerpted below may not be substantiated by competent and reliable scientific evidence.

Excerpts from www.nulifecbdoils.com/medical-applications-cbd

The Health Applications of CBD

The Many Ways in Which CBD is Increasing Health and Enhancing Lives

The cannabinoid compound, cannabidiol – otherwise known as CBD, is becoming increasingly respected and acknowledged as a powerful healing modality that treats a wide spectrum of medical conditions. With it's low to zero THC content, CBD offers powerful pain relief without the psychotropic effects of feeling "high" that go along with recreational marijuana. Extensive research has gone into the different ways in which CBD affects the endocannabinoid system of the body that regulates our immune system, sleep, nervous system and organ functions. CBD can be used to combat a wide range of medical issues and there are miraculous and positive testimonials in abundance that highlight CBD success stories.

Outlined below are some of the primary areas where CBD products have been proven to be beneficial:

- Pain relief and anti-inflammatory properties for arthritis and rheumatism
- Acne and skin conditions
- Mental disorders such as Autism, ADHD, Bipolar, Anorexia and Schizophrenia
- Addiction recovery
- Lou Gehrig's Disease (ALS)
- Anxiety, Depression and PTSD
- Neurological disorders such as Parkinson's, Alzheimer's Disease, Epilepsy Stroke, TMI's, MS and Fibromyalgia
- Cancer treatment for tumor growth inhibitors, increased appetite and pain relief
- Diabetes
- AIDS
- Digestive, Gastrointestinal and Endocrine Disorders such as IBS and Crohn's
- Sleep Disorders

Below we go into greater detail as to the specific ways that CBD impacts some of our most common ailments.

Cancer Treatment

The impetus behind creating NuLife CBD came from observing a family member's battle with terminal esophageal cancer in 2015 and how powerful and rapid a remedy CBD was during his final days. A mixture of CBD and THC supported him greatly in minimizing his pain and nausea and increasing his appetite. Using a variety of CBD products made his ultimate transition infinitely easier and less painful. Having an increased appetite and decreased nausea allowed him to maintain critical nutrition levels and keep weight on, which is important when dealing with the fallout from chemotherapy and radiation. Throughout the process of his cancer treatment, the CBD allowed him pain free nights where he was able to sleep, and in the end, it increased the overall quality of his life before passing.

According to the **National Cancer Institute**, "Cannabidiol (CBD)… may relieve pain and lower inflammation without causing the 'high' of delta-9-THC. Cannabinoids may be useful in treating the side effects of cancer and cancer treatment." CBD has also been seen as a growth inhibitor in tumors and may impact cellular dysplasia." [sic]

A Miracle Pain Remedy

Do a bit of internet research and you will discover a plethora of reviews and testimonials from people who have traded in their pharmaceutical-grade pain and anti-inflammatory medications for the all-natural benefits of CBD. CBD products are effective in treating both acute and chronic pain and can come in the form of CBD oil, CBD ointment and cannabis pain cream and gel for topical use, vaping CBD oil to be inhaled and CBD gummies, tinctures, capsules and powders to be ingested. 34-year-old Jen Barker from New Mexico had tried everything to minimize the pain she experienced each month during her menstrual cycle, often doubled over with abdominal cramping. She experienced immediate relief from her symptoms upon trying CBD capsules and after 3 months of daily usage her cycle became more manageable than ever before.

Treatment for Epilepsy and Seizures

13-year-old Emma Crozier of Arizona uses CBD to manage the epileptic seizures that have plagued her life since the age of 2. The use of high-grade Medical CBD has reduced the number of her grand mal seizures from multiple a day to one one [sic] or two per week. According to a **Consumer Reports** article, FDA-approved seizure medications "fail about one-third of all sufferers, either because the drugs don't stop the seizures or because the side effects are too severe." Epileptic seizures are caused by irregularly misfiring electrical charges within the brain, which can result in convulsions and altered or impaired states of consciousness. The specific cause of epilepsy remains unknown, but can sometimes be the result of traumatic brain or head injuries, hormonal issues or the introduction of a virus.

Treatment for Multiple Sclerosis

Multiple Sclerosis or MS is a chronic autoimmune disease that affects the central nervous system, optic nerves and brain and can be incredibly painful when patients suffer from frequent muscle spasms. CBD has been shown to reduce spasm levels and greatly lower the pain of MS side effects.

Neuroprotection Against Neurological Disorders

Extensive research is currently being conducted around the positive benefits of using CBD to treat a variety of neurological disorders that cause the degeneration of the brain and nerves over time. Patients with disorders such as Alzheimer's, Multiple Sclerosis (MS), Parkinson's disease, traumatic brain injuries and the negative effects of an ischemic attack such as a stroke have seen significant success in implementing CBD as part of their treatment plan based on its ability to reduce the inflammation that can make neurodegenerative symptoms worse.

Treatment of Depression and Other Mental Health Applications

Unlike THC, who's [sic] psychotropic effects can impact anxiety and paranoia levels, CBD has shown great promise in improved cognitive function and enhanced relief for patients suffering from a wide variety of mental disorders such as anxiety, depression, addiction, schizophrenia, bipolar disorder, OCD and PTSD.

Excerpt from www.nulifecbdoils.com/cbd-product-reviews

Reviews

Rated **5** out of 5
Adria *(verified owner)* - July 12, 2019
This cream is wonderful and has really helped my arthritis

 CBD Pain Cream – 1000mg CBD 2 Oz

Rated **5** out of 5
Peter Prinsen *(verified owner)* - June 24, 2019
I have arthritis in both feet and after using the 1000 mg product for a few days got significant relief from the pain. Orthotics has helped a little but nothing has helped as much as the cream.

 CBD Pain Cream – 1000mg CBD 2 Oz

Rated **5** out of 5
Anonymous *(verified owner)* - June 21, 2019
My blood pressure has always been high... now it is in the low normal range. Diet, Exercise–Same... Only difference is CBD.

 CBD Oil 500mg (30ml) Bottle

Excerpt from www.nulifecbdoils.com/what-is-cbd-hemp-oil-cannabidiol-information

The Most Common CBD Uses

* * *

The most common reasons that people use CBD are to provide natural pain relief and anti-inflammation for ailments that include the following:

- Joint pain from osteo and rheumatoid arthritis
- Support for neurodegenerative diseases such as alzheimers and parkinsons
- Treatment for PTSD, depression, anxiety, schizophrenia and other mental health considerations
- Support with chronic insomnia
- Support with quitting smoking and other substance use disorders
- Chronic pain from injuries
- Increased appetite, reduced nausea and pain relief for cancer patients
- Support for treatment-resistant epilepsy in both children and adults
- Support with autoimmunity for inflammatory and pain-associated disorders such as fibromyalgia and MS
- Preventative diabetes measure and effective treatment for existing Type 1

- External uses such as psoriasis and acne
- Antitumor cancer treatments for leukemia, cervical and colon cancers and combination therapy for breast and prostate cancer
- Treatment of antibiotic resistant bacteria

We strongly urge you to review all claims for your products, including consumer testimonials and product reviews, and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a federal district court injunction or an administrative cease and desist order. An order also may require that you refund money to consumers.

With regard to the advertising claims discussed above, please notify staff attorney Keith Fentonmiller via electronic mail at kfentonmiller@ftc.gov within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC staff's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Fentonmiller at 202-326-2775.

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices