Advanced Spine and Pain, LLC (d/b/a Relievus) 3/28/19

DEPARTMENT OF HEALTH
AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20993

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER
PROTECTION
WASHINGTON, D.C. 20580

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 (http://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 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 (mailto: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 (mailto:FDAADVISORY@fda.hhs.gov)**.

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

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

cc:
Relievus
904 Chicago Drive
Jenison, MI 49428

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[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 (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 (http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda)**). 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.

More in Warning Letters (/ICECI/EnforcementActions/WarningLetters/default.htm)

Nutra Pure LLC 3/28/19

DEPARTMENT OF HEALTH
AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20993

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER
PROTECTION
WASHINGTON, D.C. 20580

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 (http://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]** 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. 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.

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.

- "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 (mailto: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 (mailto:FDAADVISORY@fda.hhs.gov)**.

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

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

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[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 (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 (http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda)**.

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PotNetwork Holdings, Inc. 3/28/19

DEPARTMENT OF HEALTH
AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20993

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER
PROTECTION
WASHINGTON, D.C. 20580

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**

(http://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 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 (mailto:Shawn.Goldman@fda.hhs.gov)**.

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

/S/
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

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[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. (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 (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial)**

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