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

---

[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)**

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