PROGRAM MATERIALS
Program #29110
June 10, 2019

What's Next for CBD? (FDA Speaks)

Celesq® AttorneysEd Center
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WHAT'S NEXT FOR CBD?

June 10, 2019

Douglas R. Sargent
Ryan M. Holz
David F. Standa

Celesq AttorneysEdCenter Webcast
Chicago, Illinois

What is CBD?

- CBD is “cannabidiol,” one of many naturally occurring cannabinoids in the cannabis plant.
- CBD has no psychoactive properties.
- THC is another primary cannabinoid and creates the “high.”
- CBD and THC can be derived from either hemp or marijuana, which are simply different varieties of the cannabis plant.
- Hemp has significantly less THC and more CBD than marijuana. Marijuana has significantly more THC but less CBD than hemp.

Legal Status Before the 2018 Farm Bill

- Before the passage of the 2018 Farm Bill, both varieties of cannabis -- hemp and marijuana -- were schedule 1 controlled substances under the Controlled Substances Act.

- A schedule 1 controlled substance is a drug that cannot be prescribed or administered for medical use, is not safe, and has a high potential for abuse.

- Accordingly, before the 2018 Farm Bill, CBD was a schedule 1 controlled substance whether derived from marijuana or hemp.

The 2018 Farm Bill

- The 2018 Farm Bill descheduled hemp under the Controlled Substances Act.
- Instead, hemp is now considered an agricultural product.
- Because it is no longer a controlled substance, experimentation and research on hemp and hemp-derived CBD ***should*** be much easier.
- Similarly, hemp and hemp-derived CBD ***should*** be commercially available for use like other agricultural products.

The Complications: State/Federal Split on Legality of CBD

- Although hemp and hemp-derived CBD are now legal at the federal level, they remain illegal in many states.
- This has created significant confusion.
- Recently, a great-grandmother was arrested at Disneyworld for carrying CBD oil. CBD oil was, at least at that time, a controlled substance under Florida law.

The Complications: Hemp-Derived vs. Marijuana-Derived CBD

- Marijuana-derived CBD, as opposed to hemp-derived CBD, remains illegal at the federal level.
- There is no easy way to determine whether CBD is hemp-derived or marijuana derived.
- This creates additional confusion.
- The TSA's recent announcement is a prime example. The TSA now claims that medical marijuana is allowed on board flights. But the fine print indicates that really only hemp-derived CBD is allowed, medical marijuana and marijuana-derived CBD are not as both remain illegal at the federal level.
- This policy change is going to potentially result in more people bringing medical marijuana to airports thinking that is acceptable, and will create an impossible dilemma for TSA agents.

The Complications: FDA Jurisdiction Over CBD

- Although hemp is an agricultural product and hemp-derived CBD is technically legal, the FDA has asserted jurisdiction over CBD.
- CBD is the active-ingredient in an FDA-approved drug, Epidiolex.
- As such, it was subject to substantial clinical investigation ***before*** it was ever marketed as a food or dietary supplement.
- Under the Food, Drug, and Cosmetic Act (FD&C Act), it is illegal to introduce a drug ingredient into the interstate food supply or market it as a dietary supplement.
- As such, CBD cannot be lawfully added to foods or beverages or marketed as a dietary supplement (if such products enter the stream of interstate commerce).

The Complications: FDA Jurisdiction Over CBD

- On the same day as President Trump signed the 2018 Farm Bill, then-FDA Commissioner Scott Gottlieb issued a statement about CBD.

- He asserted the FDA's position that CBD could not be lawfully added to food and drinks or marketed as a dietary supplement.

- He also stated that the FDA "continue[s] to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds."

The Complications: FDA Jurisdiction Over CBD

- The FDA has been vague as to whether it believes that the FD&C Act prohibits CBD applications other than in food, drink, and dietary supplements.
- That includes cosmetics, ointments, topical creams, patches, and sprays containing CBD.
  - Companies have taken advantage of that grey area; those products are being marketed at major retailers throughout the country, including Walgreens and CVS.
- Food and beverage makers are attempting to evade the FD&C Act by adding CBD at the point of sale, thus limiting any potential interstate commerce concerns.
  - California, Maine, Ohio, and New York City have banned CBD in food and drinks.

The Complications: FDA Jurisdiction Over CBD

- The FDA has not been silent on CBD; it has sent out various warning letters to companies making claims regarding CBD that are not scientifically supported.
  - The FDA (in collaboration with the FTC) has issued at least three such letters this year, one last year, and four in 2017.
  - The letters were targeted at companies making claims about CBD's "ability to limit, treat or cure cancer, neurodegenerative conditions, autoimmune diseases, opioid use disorder, and other serious diseases, without sufficient evidence and the legally required FDA approval."
- But the sheer number of entities selling CBD means those efforts are a drop in the bucket.
  - The FDA has been focusing its attention on those making false or exaggerated claims regarding CBD's health effects, rather than those simply offering CBD in foods or drinks.
- The FDA faces institutional risk if it is perceived as being an ineffective regulator.

Congress Wants CBD Available

- Upon hearing Dr. Gottlieb's statement regarding the illegality of hemp-derived CBD food and drink products, Congress called him to testify.
- During February 2019 testimony, Dr. Gottlieb backtracked somewhat, indicating that the FDA "heard Congress loud and clear" with respect to hemp and hemp-derived CBD and acknowledging that CBD has some therapeutic value.
- Dr. Gottlieb announced that the FDA would hold public hearings on the safety and efficacy of hemp-derived CBD and to consider the possibility of allowing hemp-derived CBD in food and beverages.
- Dr. Gottlieb subsequently announced his resignation as FDA commissioner.

The May 31, 2019 FDA Public Hearing

- On May 31, 2019, the FDA held the promised public hearing regarding hemp-derived CBD.
- Acting FDA Commissioner Dr. Ned Sharpless reaffirmed that it is illegal to put CBD in food or market it as a dietary supplement.
- Commissioner Sharpless expressed interest in determining how much CBD is safe to consume in a day, how it interacts with other drugs, and its impact on pregnant woman and children.

The May 31, 2019 FDA Public Hearing

- The FDA heard testimony from varied sources.
- One focus was on the health benefits and side effects of CBD.
- A variety of speakers admitted that there is a lack of knowledge surrounding CBD. Some took the position that the FDA should slow down before allowing CBD in food to allow the research to catch up. Other used the lack of knowledge as a basis to argue that some of the more onerous research restrictions need to be removed.
- Other speakers disagreed, noting that there is sufficient and growing research indicating CBD is effective, and has limited side effects. One speaker referenced the WHO's 2018 review which found CBD to be safe and non-addictive (the report did not address the health benefits of CBD).
- There was repeated references to Epidiolex, the CBD-drug that the FDA approved for certain rare forms of childhood epilepsy.

The May 31, 2019 FDA Public Hearing

- Another issue was the underground market.
- Many speakers confirmed that a substantial number of CBD products being sold are untested and contain inaccurate labeling.
- Only those products sold at state-legal dispensaries generally contain what they say they contain.
- The lack of reasonable FDA guidance rewards the underground market because consumers want CBD, responsible entities are scared away from the market by the FDA, and thus irresponsible entities are filling the void.

The May 31, 2019 FDA Public Hearing

- Related to the underground market, a third theme was that the CBD genie is effectively out of the bottle—consumers want CBD and the FDA cannot stop them from getting it, so the FDA should simply focus on regulation.

- It is not clear how well this argument plays—if CBD is not safe, the fact that it is already being used is not going to convince the FDA to allow its continued use.

- But there is no doubt that the FDA is playing catch-up with respect to CBD and needs to develop a plan or risk becoming ineffectual.

What's Next for CBD in the Short Term?

- There are no guarantees for what happens next, but it appears likely that the FDA will soon issue regulations that set forth a process for allowing CBD in certain forms to be contained in food.
- The FDA will likely require testing and inspection of CBD products using a sliding scale approach depending on CBD potency and intended usage.
- The FDA will likely marry that testing and inspection approach with a crackdown on the unregulated market, so as to incentivize compliant entities to enter the market.
- The result for consumers will be a safer and more regulated product, but also one that is more expensive and more difficult to obtain, at least in the short run.

What's Next for CBD in the Long Term?

- CBD's long-term future depends on the results of more rigorous testing.
- With hemp-derived CBD legal at the federal level, state legalization of hemp and marijuana, and perhaps FDA approval for at least some form of CBD in foods and beverages, the research into CBD has and will continue to grow.
- If that research continues to show that CBD is safe and effective, the market will thrive as expected.
- If that research shows that CBD is safe, but not particularly effective, the CBD market will likely dwindle and become akin to the dietary supplement market.
- And if that research shows that CBD is not actually safe, then the FDA will intervene more stridently, CBD will likely disappear, and all that will be left will be the residual litigation.

Thank you

Douglas R. Sargent - dsargent@lockelord.com

Ryan M. Holz - rholz@lockelord.com

David F. Standa - dstanda@lockelord.com

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WARNING LETTER

Green Roads of Florida LLC

MARCS-CMS 513854 — 31/10/2017

Delivery Method: UPS

Recipient:

Laura Fuentes

Green Roads of Florida LLC

521 162nd Ave

Pembroke Pines, FL 33028

United States

Issuing Office:

San Juan District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Office of Regulatory Affairs
Office of Human and Animal Food Operations
East Division IV
Compliance Branch
466 Avenida Fernández Juncos
San Juan, Puerto Rico 00901-3223
Tel: (787) 729-8500

October 31, 2017

WARNING LETTER

18-HAFE4-WL-02 / CMS No.513854

VIA UNITED PARCEL SERVICE

NEXT DAY - SIGNATURE REQUIRED

Ms. Laura Fuentes
Greenroads Health
Green Roads of Florida LLC
15757 Pines Blvd., Ste. 178
Pembroke Pines, Florida 33027-1207

Dear Ms. Fuentes:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web site at the Internet address www.Greenroadhealth.com (http://www.Greenroadhealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in February 2017, and has determined that you take orders there for the following cannabidiol (CBD) products: "CBD Oil" (100mg, 250mg, 350mg, 550mg), "CBD Tincture" (1000mg and 1500mg), "CBD Oil 100mg + Terpenes Flavor", "CBD capsules 100mg", "CBD Crumble 250mg", "Chamoile Calming Tea" (with CBD), "CBD Edibles Gummie Blocks 60mg", "CBD Edibles Jollies 30mg", "CBD Edibles Gummie Men 60mg", "CBD Edibles Lollypops 30mg", "CBD Pain Be Gone" Cream 150mg, "CBD Shatter 450mg", "CBD Dab Wax 250mg", "CBD Dab Crystal 250mg", and "CBDreem" (Cannabidiol syrup). The claims on your website establish that the 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 diagnosis, 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/).

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

- "CBD .[has] anti-proliferative properties that inhibit cell division and growth in certain types of cancer, not allowing the tumor to grow."
- "Almost all studies recognize CBD's potential in preventing both cancer spread and growth..."
- "The following are some of the many ailments CBD oil can potentially be therapeutic for: asthma, Alzheimer's disease, arthritis, autism, bipolar disorder, various types of cancer . . ."
- "...considering the lack of risks associated with CBD it is an attractive alternative or addition to anyone's treatment for Alzheimer's disease."
- "Adding CBD oil as part of your daily Alzheimer's medicine routine has a good chance at delaying the progression of the disease..."
- "[CBD] has antipsychotic properties, which makes it very useful for treating bipolar disorder."

Your products 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 FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 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 "CBD Oil" (100mg, 250mg, 350mg, 550mg), "CBD Tincture" (1000mg and 1500mg), "CBD Oil 100mg + Terpenes Flavor", "CBD capsules 100mg", "CBD Crumble 250mg", "Chamoile Calming Tea" (with CBD), "CBD Edibles Gummie Blocks 60mg", "CBD Edibles Jollies 30mg", "CBD Edibles Gummie Men 60mg", "CBD Edibles Lollypops 30mg", "CBD Pain Be Gone" Cream 150mg, "CBD Shatter 450mg", "CBD Dab Wax 250mg", "CBD Dab Crystal 250mg" and "CBDreem" (Cannabidiol syrup) 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, "CBD Oil" (100mg, 250mg, 350mg, 550mg), "CBD Tincture" (1000mg and 1500mg), "CBD Oil 100mg + Terpenes Flavor", "CBD capsules 100mg", "CBD Crumble 250mg", "Chamoile Calming Tea" (with CBD), "CBD Edibles Gummie Blocks 60mg", "CBD Edibles Jollies 30mg", "CBD Edibles Gummie Men 60mg", "CBD Edibles Lollypops 30mg", "CBD Pain Be Gone" Cream 150mg, "CBD Shatter 450mg", "CBD Dab Wax 250mg", "CBD Dab Crystal 250mg" and

"CBDreem" (Cannabidiol syrup) fail to bear adequate directions for their intended use 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)].

Further, 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 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. According to your product labeling, "Chamoile Calming Tea" (with CBD), "CBD Edibles Gummie Blocks 60mg", "CBD Edibles Jollies 30mg", "CBD Edibles Gummie Men 60mg", and "CBD Edibles Lollypops 30mg" are food products which contain cannabidiol (CBD). Therefore, the introduction or delivery for introduction into interstate commerce of those products is a prohibited act under section 301(ll) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which each such item will be corrected.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. If you have any questions concerning this letter, please contact Ms. Pearl Gonzalez, Compliance Officer, at (407) 475-4730. Your written response to this letter should be sent to: Ms. Maridalia Torres, District Director, Food and Drug Administration, Office of Human and Animal Food Operations East Division IV, 466 Fernández Juncos Avenue, San Juan, PR 00901-3223.

Sincerely yours,
/S/
Maridalia Torres-Irizarry
Director San Juan District
Program Division Director OHAFO IV East

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WARNING LETTER

Natural Alchemist

MARCS-CMS 513852 — 31/10/2017

Recipient:

Will Claren

Natural Alchemist

3941 Park Drive, Suite 279
El Dorado Hills, CA 95762
United States

Issuing Office:

Los Angeles District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Office of Human and Animal Food Division 5 West
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

October 31, 2017

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Natural Alchemist
Alurent, Inc
Attn: Will Claren, CEO
3941 Park Drive
Suite 279
El Dorado Hills, CA 95762

Dear Mr. Will Claren:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.natural-alchemist.com (http://www.natural-alchemist.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in September 2017 and has determined that you take orders there for the products "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg, and "Natural Alchemist 300mg Hemp Oil drops," all of which you claim contain cannabidiol (CBD). FDA also reviewed your website at the Internet address www.cbd-now.com (http://www.cbd-now.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and determined that you take orders there for the product "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg. Furthermore, www.cbd-now.com (http://www.cbd-now.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) directs consumers to purchase Natural Alchemy CBD products online by "[logging] on to the Natural Alchemy CBD website," which we understand to be a reference to www.natural-alchemist.com (http://www.natural-alchemist.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). The claims on www.cbd-now.com (http://www.cbd-now.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) establish that your "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg, and "Natural Alchemist 300mg Hemp Oil drops" products are drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the 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 Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov (http://www.fda.gov/).

Although you market "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg and "Natural Alchemist 300mg Hemp Oil drops" as dietary supplements, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if an article (such as CBD) 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.

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 [21 U.S.C § 355]. 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 section 201(ff)(3)(B)(ii) of the Act, but you may present FDA with any evidence that has bearing on this issue.

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

- "Combats tumor and cancer cells"
- "Cannabinoids are found to have particular application . . . in limiting neurological damage following stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease."
- "Study: Cannabinoids a Potential Treatment Option for Chemotherapy-Induced Hearing Loss"
- " [C]annabis plant, enriched with CBD, can be used for treating diseases like rheumatoid arthritis, colitis, liver inflammation, heart disease and diabetes."
- "CBD may have therapeutic benefits in the treatment of various conditions, including . . . rheumatoid arthritis, schizophrenia, diabetes . . . alcoholism, strokes and cardiovascular disease, cancer, and other ailments."
- "People who benefit from cannabidiol: . . . Lupus, L[y]me Disease; Stroke Victims"

Testimonial

- "I was pleasantly surprised to find that CBD helped my arthritis...I have shared with my son and he states he is a big believer in CBD for . . . TBI [traumatic brain injury] after being acquainted with military personnel who have tried it."

Your products 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 FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 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 "Herbal Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg, and "Herbal Alchemist 300mg Hemp Oil drops" 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, "Herbal Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg, and "Herbal Alchemist 300mg Hemp Oil drops" fail to bear adequate directions for their intended use 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)]. The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which each such item will be corrected.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. You may respond in writing to Matthew Walburger, Acting Director of Compliance at 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions concerning this letter, please contact Tammy Hancock, Compliance Officer at 510-337-6737.

Sincerely yours,
/S/
Darla R. Bracy, District Director
Office of Human and Animal Food
Division 5 West

cc:
Natural Alchemist/Alurent Inc.
Attn: Will Claren
3565 South Las Vegas Blvd
Suite 392
Las Vegas, NV 89109

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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-… (https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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-inves… (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Close Out Letter

- Natural Alchemist - Close Out Letter 7/3/18 (/ucm612780)

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WARNING LETTER

Stanley Brothers Social Enterprises, LLC

MARCS-CMS 490089 — 31/10/2017

Recipient:

Joel Stanley

Stanley Brothers Social Enterprises, LLC

3515 N. Chestnut Street
Colorado Springs, CO 80907
United States

Issuing Office:

Los Angeles District Office

United States

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine, CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417

WARNING LETTER

VIA SIGNATURE CONFIRMED DELIVERY

October 31, 2017

Joel Stanley, CEO
Stanley Brothers Social Enterprises, LLC
d/b/a CW Botanicals
d/b/a CW Hemp
3515 N. Chestnut Street
Colorado Springs, CO 80907

Dear Mr. Stanley:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.cwbotanicals.com (http://www.cwbotanicals.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (redirects to www.cwhemp.com (http://www.cwhemp.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) in August 2017 and has determined that you take orders there for the products "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," "Everyday Advanced Dietary Supplement" and "Charlotte's Web Gel Pen," which you promote as products containing cannabinoids, including cannabidiol (CBD). We have also reviewed your website at the internet address www.theroc.us (http://www.theroc.us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), and your social media websites at www.facebook.com/CWHempOfficial (http://www.facebook.com/CWHempOfficial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and www.twitter.com/CWHemp (http://www.twitter.com/CWHemp) (http://www.fda.gov/about-fda/website-policies/website-disclaimer); these websites direct consumers to your website, www.cwhemp.com (http://www.cwhemp.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), to purchase your products. The claims on your websites establish that the products are drugs under section 201 (g)(1) of the Federal Food, Drug, and Cosmetic Act (the 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 Act. You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov (http://www.fda.gov/).

Although you market "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," and "Everyday Advanced Dietary Supplement" as dietary supplements, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if an article (such as CBD) 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.

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 section 201(ff)(3)(B)(ii) of the 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 www.cwhemp.com (http://www.cwhemp.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that establish the intended use of your products as drugs include, but may not be limited to, the following:

On the webpage titled "Everyday Advanced Hemp Oil":

- "A patient of mine uses this for Cancer and it gives lots better relief than prescription drugs!"
- "My dear ex mother in law has been diagnosed with late stage pancreatic cancer. This is the only thing that gives her relief."
- "Excellent Results For My TBI . . . "[2]
- ·"I have been severely depressed . . . [s]o I started taking this product . . . I have gone from basically clinically depressed to feeling ok about life in general. It's been a miracle for me compared to how I use to feel."

You also direct consumers to the Realm of Caring website at www.theroc.us (http://www.theroc.us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).[3]

Examples of claims observed on www.theroc.us (http://www.theroc.us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that establish the intended use of your products as drugs include, but may not be limited to, the following:

On a webpage titled "Cancer Dosing Guidelines":

- "Realm of Caring Recommends: Adult cancer clients take 50 mg of CBD 2x daily (100 mg/day) . . . Child cancer clients take 25 mg of CBD 2x daily (50 mg/day)"
- "[C]urrent studies have reported that CBD is showing promise in how oncologists are looking to treat breast, glioma, Leukemia, thyroid, colon and lung cancer."
- "The type of dosing that is recommended for clients in partial or complete remission is called 'maintenance dosing' and . . . hopefully keeping cancer at bay. Clients using maintenance dosing will likely be using much lower levels of cannabinoid intake than if they were actively trying to fight cancer."
- "Adult cancer remission clients take 100 mg of CBD 2x daily . . . Pediatric cancer remission clients take 25 mg of CBD 2x daily, go up to 1mg/lb of body weight"

On the webpage titled "Forums":

Topic "Metastatic Breast Cancer" – posting by a representative of Realm of Caring:

- "The reported benefits of Charlotte's Web™ Hemp Oil include . . . anti-tumoral . . . "

Topic "Diabetes" – posting by a representative of Realm of Caring:

- "The Charlotte's Web Products™ Everyday Advanced 5000 is best for clients with chronic conditions and has a higher concentration of CBD at 50mg/ml."
- "Charlotte's Web™ Everyday 5000 is high in CBD . . . [r]esearch is showing CBD to have a wide range of benefits. These include . . . anti-cancer . . ."

On a webpage titled "Research library", there are links to articles hosted on www.theroc.us (http://www.theroc.us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that promote CBD for diseases including but not limited to Alzheimer's disease, Breast Cancer, Diabetes, Leukemia, Lung Cancer, Parkinson's disease, Stroke and others.

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

www.facebook.com/CWHempOfficial (http://www.facebook.com/CWHempOfficial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- On June 28, 2016: "Who can write an rx script for my 17 year old son with dx PDD-NOS/Autism? Where can I purchase CW?" CW Hemp replied: "Charlotte's Web™ . . . [y]ou can order right from our site at cwhemp.com . . . you do not need a RX to buy Charlotte's Web . . ."
- On May 21, 2016: "[L]earn how #CharlottesWeb could help #CTE and concussions in athletes!"[4]

https://twitter.com/CWHemp (https://twitter.com/CWHemp) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- September 17, 2016 retweeted posting – "The NFL Could End CTE With a Strain of Marijuana . . . A cannabidiol-rich strain – Charlotte's Web – won't get players high, but it can protect their brains."
- May 17, 2016 posting – "#Boxing #Concussions #CTE could all benefit from Charlotte's Web #Hemp extracts #WhyCW . . ."

The claims on your websites establish that the products are drugs under section 201(g)(1) of the 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 "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," "Everyday Advanced Dietary Supplement" and "Charlotte's Web Gel Pen" 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 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), 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 "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," "Everyday Advanced Dietary Supplement" and "Charlotte's Web Gel Pen" 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, "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement" and "Charlotte's Web Gel Pen" 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)].

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.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing 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 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 refer to the Warning Letter Number above (**490089**). Please address your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild
Irvine, California 92612

If you have questions regarding any issues in this letter, please contact CDR Matthew R. Dionne, Compliance Officer via email at Matthew.Dionne@fda.hhs.gov (mailto:Matthew.Dionne@fda.hhs.gov), or by phone at (303) 236-3064 and reference unique identifier **490089**. Electronic responses may be sent to CDR Dionne at the email address provided.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

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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-… (https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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-inves… (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

[2] TBI is an abbreviation for Traumatic Brain Injury.

[3] Your website at www.cwhemp.com (http://www.cwhemp.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and your social media websites at www.facebook.com/CWHempOfficial (http://www.facebook.com/CWHempOfficial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and www.twitter.com/CWHemp (http://www.twitter.com/CWHemp) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) direct consumers to the Realm of Caring at www.theroc.us (http://www.theroc.us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Although your firm claims that the Realm of Caring is a separate entity, both organizations appear to be operating an integrated distribution program. For example, throughout your cwhemp.com website, you state that your products are "Realm of Caring Approved" and you direct consumers to the Realm of Caring for resources pertaining to your products. Your website also states that the Realm of Caring offers many resources that pertain to your product, including personal testimonies from your customers. The Realm of Caring's website prominently displays "Charlotte's Web™" as a brand of products that they have approved. Furthermore, your firm's June 8, 2015 Facebook posting states that you started the Realm of Caring in order to make claims about your products ("[W]e started the Realm of Caring . . . [t]hey can consult you on conditions like Crohns, arthritis, pain, behavioral disorders and more. They also offer a generous discount on #CharlottesWeb products. It's worth a try! Go to www.theroc.us (http://www.theroc.us) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).").

[4] CTE is an abbreviation for chronic traumatic encephalopathy. CTE is a degenerative brain disease caused by repetitive brain trauma.

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WARNING LETTER

That's Natural

MARCS-CMS 513302 — 31/10/2017

Recipient:

Tisha T. Casida

That's Natural

1706 Hollywood Drive
Pueblo, CO 81005
United States

Issuing Office:

Los Angeles District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine, CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417

WARNING LETTER

VIA SIGNATURE CONFIRMED DELIVERY

October 31, 2017

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

Tisha T. Casida
That's Natural! Marketing & Consulting
1706 Hollywood Drive
Pueblo, CO 81005

Dear Ms. Casida,

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at www.cbdoil.life (http://www.cbdoil.life) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in August 2017 and has determined that you take orders there for the products "CBD All-Natural Hemp Oil," "Bosom Lotion Potion," and "CBD-Rich Healing Crème," all of which you claim to contain cannabidiol (CBD). FDA also reviewed your social media websites at www.facebook.com/ThatsNaturalCBDoil (http://www.facebook.com/ThatsNaturalCBDoil) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and at www.twitter.com/PureCBDHempOil (http://www.twitter.com/PureCBDHempOil) (http://www.fda.gov/about-fda/website-policies/website-disclaimer); these websites direct consumers to your website, www.cbdoil.life (http://www.cbdoil.life) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), to purchase your products. The claims on your websites establish that your 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 diagnosis, 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/).

Unapproved New Drugs and Misbranded Drugs

Although you market "CBD All-Natural Hemp Oil" as a dietary supplement, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if an article (such as CBD) 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.

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 [21 U.S.C. § 355]. 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 section 201(ff)(3)(B)(ii) of the Act, but you may present FDA with any evidence that has bearing on this issue.

Based on the labeling claims on your websites, your marketed products, "CBD All-Natural Hemp Oil," "Bosom Lotion Potion," and "CBD-Rich Healing Crème," are drugs under section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)] because they are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Examples of claims observed on your website www.cbdoil.life (http://www.cbdoil.life) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that establish the intended use of your CBD products as drugs include, but may not be limited to, the following:

On the webpage titled "Testimonials":

- "Scientific research by doctors have shown it actually kills cancer cells and provides a protective coating around our brain cells."
- "as a Type 1 diabetic, my blood sugars have noticeably leveled off."
- "My blood pressure and heart rate have also significantly improved as well."

On the webpage titled "The Major Terpenes in That's Natural Full-Spectrum CBD-Rich Hemp Oil":

- Ingredient Beta-Caryophyllene is "anti-tumor . . . "
- Ingredient Beta-Myrcene "is anti-tumor . . . "
- Ingredient D-Limonene is "anti-tumor . . . "
- Ingredient Humulene "is anti-tumor . . . "

On the webpage titled "What Is CBD Hemp Oil?":

- "CBD makes cancer cells commit 'suicide' without killing other cells"

- "CBDs are effective against MRSA (antibiotic-resistant bug)"

On the webpage titled "Research on Cannabinoids for Breast Cancer" where you advertise "Bosom Lotion Potion":

- "Non-psychoactive cannabinoids (like CBD) may have therapeutic effects for the human body, through the Endocannabinoid System (ECS). This includes treating tumors and cancer-related pain."

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

www.facebook.com/ThatsNaturalCBDoil (http://www.facebook.com/ThatsNaturalCBDoil) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- December 7, 2016 posting – "There's even more applications, including: . . . #breastcancer #tbi #concussions . . ."[2]
- November 29, 2016 posting – "Non-Psychoactive cannabinoids like CBD (Cannabidiol) may be effective in treating tumors from cancer – including breast cancer."

www.twitter.com/PureCBDHempOil (http://www.twitter.com/PureCBDHempOil) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- November 13, 2016 posting – "Research from Molecular Cancer Therapeutics - CBD for Cancer Cells"
- August 22, 2016 posting – "Research showing benefits of cannabinoids for #breastcancer"
- August 22, 2016 posting – "Research showing benefits of cannabinoids for your #heart . . . #atherosclerosis"
- August 22, 2016 posting – "Research showing benefits of cannabinoids for #autism"
- August 20, 2016 posting – "Research showing benefits of cannabinoids for #alzheimers"

Your products "CBD All-Natural Hemp Oil," "Bosom Lotion Potion," and "CBD-Rich Healing Crème" 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 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 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 "CBD All-Natural Hemp Oil," "Bosom Lotion Potion," and "CBD-Rich Healing Crème" 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. Thus, your products "CBD All-Natural Hemp Oil," "Bosom Lotion Potion," and "CBD-Rich Healing Crème" fail to bear adequate directions for their intended uses and, therefore, the products are misbranded within the meaning of 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)].

The violations cited in this letter are not intended to be an all-inclusive statement 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 assure that you comply 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.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related

documentation. If you cannot complete corrective actions within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should refer to the Warning Letter Number above (513302). Please address your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild
Irvine, California 92612

If you have questions regarding any issues in this letter, please contact CDR Matthew R. Dionne, Compliance Officer via email at Matthew.Dionne@fda.hhs.gov (mailto:Matthew.Dionne@fda.hhs.gov), or by phone at (303) 236-3064 and reference unique identifier 513302. Electronic responses may be sent to CDR Dionne at the email address provided.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

cc:

Tisha T. Casida
That's Natural! Marketing & Consulting
P.O. Box 8944
Aspen, CO 81612

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[1] *See* https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-… (https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer); and https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-inves… (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
[2] TBI is an abbreviation for traumatic brain injury.

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WARNING LETTER

Signature Formulations, LLC

MARCS-CMS 545017 — 31/07/2018

Recipient:

Mr. John R. Rose

Signature Formulations, LLC

5446 W. Roosevelt St., Suite 101
Phoenix, AZ 85043
United States

Issuing Office:

San Francisco District Office

United States

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine, CA 92612
Telephone: (949) 608-2900
Fax: (949) 608-4417

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

July 31, 2018

Mr. John R. Rose
President
Signature Formulations LLC

5446 W. Roosevelt St., Suite 101
Phoenix, AZ 85043

Dear Mr. Rose:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Signature Formulations LLC (FEI 3011368010), at 5446 W. Roosevelt St., Suite 101, Phoenix, AZ from October 24 to November 9, 2017.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

In addition to the CGMP violations, your firm also manufactures unapproved new and/or misbranded drug products. During the inspection, the investigator collected labeling for Herbal Muscle Gel, Herbal Muscle Mist, and CBD Muscle Gel products. FDA also reviewed your websites at www.sigform.com (http://www.sigform.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and www.cbdtechcenter.com (http://www.cbdtechcenter.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) where the products Herbal Muscle Gel; Herbal Muscle Mist; CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and/or CBD Toothpaste are available for purchase. Your products mentioned above are unapproved new drugs in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a). Furthermore, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste are also misbranded drugs in violation of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act.

We reviewed your December 1, 2017, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

CGMP Violations

1. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).

Your firm released finished over-the-counter (OTC) topical pain relief drug products (Herbal Muscle Gel, CBD Muscle Gel, and Herbal Muscle Mist) without testing to determine conformance with their assay specifications or active ingredient label claims. In addition, your firm failed to establish product release specifications for your finished drug products.

In your response, you state that you tested retention samples from one distributed lot of each drug product noted above and that each of the tested lots met label claims. Your response is inadequate. You did not provide a scientific rationale for the limited testing you performed. Testing only a single lot of each of these drugs from **(b)(4)** does not demonstrate that all of the lots of these products you manufactured and released met their label claims.

In response to this letter, we request that you provide:

- The quality control test methods and specifications you rely upon to analyze each of your finished OTC drug products before making batch release decisions;
- An action plan and timelines for testing retained samples of all finished OTC drug products distributed and within expiry to determine the identity and strength of active ingredients. If such testing reveals that you released drug products that did not meet specifications for identity or strength of active ingredients, indicate what corrective actions you have taken or will take, such as notifying customers or recalling products.

2. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all drug products and with the responsibility for approving or rejecting procedures or specifications impacting on the identity, strength, quality, and purity of the drug products. (21 CFR 211.22(a) and (c)).

Your quality unit released drug products even though it had no assurance that products met specifications or were manufactured under adequate controls. Your quality unit failed to ensure that procedures for numerous drug manufacturing operations, such as production, cleaning, sampling plans, and testing, were drafted and approved. In addition, your quality unit did not approve finished drug product specifications.

In your response, you state that you are in the process of establishing drug product specifications and sampling plans. You state that you have prepared written procedures describing the production process for each of your drug products. We acknowledge your statement that you hired a CGMP consultant and a "**(b)(4)**" to bring your facility into CGMP compliance.

Your response cannot be fully evaluated because you failed to provide documentation and sufficient details about your firm's plan to establish appropriate drug product specifications and manufacturing procedures.

In response to this letter, we request that you provide your plan for establishing adequate quality systems. Include your approved written procedures and drug product specifications.

See FDA's guidance document, *Quality Systems Approach to Pharmaceutical CGMP Regulations*, for help implementing modern quality systems and risk management approaches to meet the requirements of CGMP regulations (21 CFR, parts 210 and 211), at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070337.pdf. (/media/71023/download)

3. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to establish the reliability of component supplier analyses on which you rely in lieu of certain tests through appropriate validation of the supplier's test results at appropriate intervals (21 CFR 211.84(d)(1)&(2)).

Your firm failed to test incoming components used in manufacturing your finished OTC drug products **(b)(4)**, and your products labeled as homeopathic drug products **(b)(4)** to determine identity, purity, strength, and quality.

Instead, your firm used results from your suppliers' certificates of analysis (COA) without establishing the reliability of your suppliers' analyses through appropriate validation, and without conducting at least one specific identity test on each incoming lot of components. Under 21 CFR 211.84(d)(2), you may not rely on your suppliers' COA to verify the identity of your components.

In your response, you state that you have validated your suppliers' COA. You also state that you will conduct identity testing of active ingredients prior to approving them for use in drug manufacturing.

Your response cannot be fully evaluated because you did not provide sufficient details regarding the validation of your suppliers' COA. You did not address your failure to test all components, including both active *and* inactive ingredients, for identity and other appropriate specifications prior to use. Also, you did not address the effect of this deficiency on the quality of all your drug products.

In response to this letter, provide:

- A retrospective review for all drug product lots, within expiry and in distribution, manufactured using components that were not adequately tested and controlled. Based on your review, indicate any corrective actions and preventive actions you have taken, including a recall of affected products, if appropriate.
- Your procedure to test incoming components.
- A detailed description of how you plan to test each component for conformity with all appropriate written specifications for identity, purity, strength, and quality. Explain how you intend to perform at least one identity test for all incoming components used in your drug product. If you accept your suppliers' COA in lieu of testing components for purity, strength, and quality, specify how you plan to establish the reliability of your suppliers' test results through validation at appropriate intervals.

4. Your firm failed to establish and follow adequate written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).

You do not have cleaning procedures for the equipment you use to manufacture multiple drug products. You have not validated the methods you use to clean your equipment. Your firm manufactures both oral and topical products, and some of these products contain **(b)(4)**. Inadequate removal of residues from manufacturing equipment during cleaning can lead to cross-contamination of products subsequently manufactured on the non-dedicated equipment.

In your response, you state that you will draft procedures for cleaning the manufacturing equipment and validate your cleaning procedures.

Your response is inadequate because you failed to assess the risk of potential cross-contamination and its effects on product quality.

In response to this letter, we request that you provide:

- Your equipment cleaning procedures and cleaning validation report to demonstrate the adequacy of your cleaning procedures.
- Your evaluation of all drug product lots, within expiry and in distribution, identifying the effects of any cross-contamination that may have occurred.

5. Your firm failed to establish and follow a written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).

You do not have stability data to support your firm's two-year expiration date for your OTC drug products, Herbal Muscle Gel, CBD Muscle Gel, and Herbal Muscle Mist. You failed to demonstrate that the chemical and physical properties of your drug products remain acceptable throughout the labeled two-year expiry period. Therefore, there is no assurance that your drug products can meet their label claims through their expiration period.

In your response, you state that you conducted informal testing or observation to support the expiration date of your OTC drug products, and that you have now established a formal stability plan to evaluate and verify the stability characteristics of your formulation and container-closure system.

Your response cannot be fully evaluated because you did not include your stability test results to demonstrate that each of your drug products met its specifications at the end of the labeled expiration period.

In response to this letter, you should provide an adequate written stability testing program and results to support your assigned expiration dates.

Unapproved New Drug Violations for OTC Drug Products

Herbal Muscle Gel and Herbal Muscle Mist are drugs within the meaning of Section 201(g)(1)(B) of the FD&C Act because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body. Specifically, these products are intended for use as external analgesics and for the treatment of other diseases (including but not limited to gout, cold, and flu).

Examples of claims observed on your products' labels and on your website, www.sigform.com (http://www.sigform.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), include the following claims that demonstrate the intended uses for Herbal Muscle Gel and Herbal Muscle Mist as drugs, as defined in section 201(g). This list is not inclusive of all claims demonstrating the products' intended uses.

Herbal Muscle Gel

Statements that appear on the product label:

- Helps reduce...Inflammation...Arthritis...Back Pain...Muscle Aches...Joints
- Try it on: ● Fibromyalgia Pain ● Carpal Tunnel ● Sciatica ● Tendonitis ● Muscle Cramps ● Sports Injuries ● Heel Spurs ● Sore/Achy Feet ● Tired Legs ● Gout
- Directions...Rub into temples to help with headaches, and chest to relieve cold and flu. Apply prior to a workout or sports activity.

Statements that appear on the website, www.sigform.com (http://www.sigform.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer):

- MSM (methylsulfonylmethane) provides sulfur and methy [sic] groups that are used for healing and repair by our joints and connective tissue. Clove Oil and Sweet Birch Oil may help to stimulate circulation

and reduce tension and spasms in muscles. Also included are the essential oils of peppermint and eucalyptus to help reduce inflammation and soothe aching feet and irritated nerves.

Herbal Muscle Mist

Statements that appear on the product label:

- Try it on: ● Fibromyalgia Pain ● Carpal Tunnel ● Sciatica ● Tendonitis ● Muscle Cramps ● Sports Injuries
- Restores Blood Flow
- DIRECTIONS: Rub into temples to help with headaches. Spray onto chest to relieve cold and flu. Apply prior to a workout or sports activity.

Statements that appear on the website, www.sigform.com: (http://www.sigform.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- Included in the Herbal Muscle Mist formula are menthol and camphor for pain relief, invigoration of tired muscles and joints, and cramps. MSM (methylsulfonylmethane) provides sulfur and methy (sic) groups that are used for healing and repair by our joints and connective tissue. Clove Oil and Sweet Birch Oil may help to stimulate circulation and reduce tension and spasms in muscles. Also included are the essential oils of peppermint and eucalyptus to help reduce inflammation and soothe aching feet and irritated nerves.

Drug products intended for external analgesic indications such as the temporary relief of minor aches and pains of muscles and joints are being evaluated under the developing monograph for Over-the-Counter (OTC)External Analgesic Drug Products for Over-the-Counter Human Use ("External Analgesic TFM" or "TFM") (48 FR 5852, February 8, 1983). Pending the promulgation of a final monograph, the agency generally does not intend to object to the marketing of products that meet both the proposed formulation and labeling conditions outlined in the TFM and each general condition in 21 CFR 330.1 unless a particular product poses a public health concern. Such marketing, however, is subject to the risk that a final rule may require reformulation and/or relabeling or FDA approval through the "new drug" procedures of the FD&C Act (section 505).

The formulation and labeling for Herbal Muscle Gel and Herbal Muscle Mist are not consistent with the conditions proposed in the External Analgesic TFM (see 48 FR 5852 at 5868). According to 21 CFR 201.66(b)(2), an active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. Although your firm does not specifically list MSM (methylsulfonylmethane), clove oil, sweet birch oil, and essential oils of peppermint and eucalyptus as active ingredients in your products, the claims on your website pertaining to these specific ingredients, as described above, demonstrate that they are active ingredients as defined in 201.66(b)(2) because the ingredients are intended to furnish pharmacological activity.

MSM (methylsulfonylmethane), sweet birch oil, eucalyptus oil, and clove oil are not proposed as active ingredients in the External Analgesic TFM. Eucalyptus oil is not included as an active ingredient in the OTC Drug Review for the indications intended for your product, and it is explicitly not permitted as an active ingredient in an OTC external analgesic drug product for counterirritant use without an FDA-approved new drug application (*see* 21 CFR 310.545(a)(10)(ii)).

Lastly, while camphor, a labeled active ingredient in both of your products, is an active ingredient included in the External Analgesic TFM, the proposed allowable dosage range for camphor in the TFM is 3-11% (48 FR 5862 at 5868). Your products' label identifies camphor at a dosage of 2%, which is outside the range which FDA proposed to be generally recognized as safe and effective for use in an external analgesic product Further, the external analgesics TFM does not propose that camphor is generally recognized as safe and effective to treat fibromyalgia pain, carpal tunnel, sciatica, tendonitis, heel spurs, gout, headaches, or cold and flu, which are included in the labeling for Herbal Muscle Gel, or fibromyalgia pain, carpal tunnel, sciatica, tendonitis, headaches, cold and flu, or restoring blood flow, which are included in the labeling for Herbal Muscle Mist.

Your products are also labeled for the treatment of gout, cold, and flu. Treatment of gout is not a condition that is included in the OTC Drug Review. Although FDA has established an OTC monograph for indications related to cold and flu (see 21 CFR Part 341), the active ingredients in your products are not included in the relevant monograph.

Furthermore, we are not aware of any adequate and well controlled clinical trials in the published literature that support a determination that Herbal Muscle Gel and Herbal Muscle Mist are generally recognized as safe and effective for their labeled indications.

Herbal Muscle Gel and Herbal Muscle Mist, as labeled, are therefore new drugs within the meaning of section 201(p) of the FD&C Act because they are not generally recognized among scientific experts as safe and effective for the drug uses described in their labeling. "New drugs" may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FD&C Act is in effect for the drug. Herbal Muscle Gel and Herbal Muscle Mist are not the subjects of approved new drug applications; therefore, marketing these products in the United States is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d) and violates section 505 of the FD&C Act.

Unapproved New and Misbranded Drug Violations for Products Purporting to Contain Cannabidiol (CBD)

The Agency reviewed the product label of CBD Muscle Gel obtained during the FDA inspection of your facility. In addition, we reviewed your website www.cbdtechcenter.com (http://www.cbdtechcenter.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) where you market and take orders for your products CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste. You promote these products as containing cannabidiol (CBD). The claims on your website 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 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/).

Although you market CBD Oil 100mg, 250mg, 500mg, and 1000mg, and CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg as dietary supplements, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(ii). Under that provision, if an article (such as CBD) 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.

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 FD&C 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 section 201(ff)(3)(B)(ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.

Claims on your website www.cbdtechcenter.com (http://www.cbdtechcenter.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that document the intended use of your products as drugs include, but are not limited to, the following:

- "For hundreds of years, people have used preparations made from C. Sativa, including CBD for a variety of disorders, including gout, rheumatism, malaria, pain, and fever."
- "[P]eople have reported reduced pain or positive results from taking CBD as a dietary supplement for ailments and neurological disorders such as . . . Alzheimer's Disease . . . Cancer . . . Crohn's Disease . . . Diabetes . . . Fibromyalgia . . . Glaucoma . . . Gout . . . HIV Dementia . . .. . . Parkinson's Disease . . . Rheumatism . . . Schizophrenia . . . Stress Disorders like PTSD . . ."
- In the product description for CBD Muscle Gel: "Fast absorbing gel reduces inflammation and pain quickly with triple active ingredients. Our gel combines the natural anti-inflammatory power of CBD with the soothing effects of Camphor and Menthol. CBD Gel helps relieve arthritis pain and sore, overworked muscles."

Claims on the label of CBD Muscle Gel that demonstrate its intended use as a drug:

- "Hand crafted with the most effective herbal ingredients for rapid relief of aching, painful joints, muscles and tissues."

- "Uses: For the temporary relief of minor aches and pains at muscles and joints associated with sore muscles, strains, joint discomfort & arthritis."

The claims on your website 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 because they are intended to affect the structure or any function of the body.

Your products, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste, 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), 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, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste, 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, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste 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).

Conclusion

Violations cited in this letter are not intended as an all-inclusive list of violations that exist in connection with your marketed products. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing 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.

We acknowledge your plan to cease drug manufacturing until you implement appropriate CGMP controls. If you resume drug manufacturing, please notify the FDA in advance so that we may verify your firm's compliance with CGMP prior to product distribution. Notify this office in writing of the specific steps that you have taken to correct violations and prevent recurrence. Provide supporting documentation.

Until the CGMP violations are corrected and we confirm your compliance, we may withhold approval of pending drug applications listing your facility. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.

After you receive this letter, you should respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. 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 actions within 15 working days, state your reasons for delay and your schedule for completion.

Please reference unique identifier CMS 545017 on all correspondence.

Send your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Irvine, CA 92612

If you have questions regarding any issues in this letter, please contact Mr. William V. Millar, Compliance Officer, at (510) 337-6896, or william.millar@fda.hhs.gov (mailto:william.millar@fda.hhs.gov).

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

[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-… (https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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-inves… (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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WARNING LETTER

Advanced Spine and Pain, LLC

MARCS-CMS 565256 — 28/03/2019

Product: Drugs

Recipient:

Young J. Lee, MD

President

Advanced Spine and Pain, LLC

813 East Gate Dr. Suite B

Mount Laurel, NJ 08054-1238

United States

Issuing Office:

United States

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 (http://www.relievuscbdoil.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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 (http://www.relievus.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), and your social media websites at www.facebook.com/Relievus/ (http://www.facebook.com/Relievus/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and https://twitter.com/Relievus (https://twitter.com/Relievus) (http://www.fda.gov/about-fda/website-policies/website-disclaimer); these websites direct consumers to your website, www.relievuscbdoil.com (http://www.relievuscbdoil.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), 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] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftn1) 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: (http://www.relievuscbdoil.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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: (http://www.relievuscbdoil.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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: (http://www.relievuscbdoil.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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: (http://www.relievus.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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/ (http://www.facebook.com/Relievus/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) and Twitter (https://twitter.com/Relievus (https://twitter.com/Relievus) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)) 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: (http://www.relievuscbdoil.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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: (http://www.relievuscbdoil.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftnref1) 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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)). 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.

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WARNING LETTER

Nutra Pure LLC

MARCS-CMS 567714 — 28/03/2019

Product: Drugs

Recipient:

CJ Montgomery

Nutra Pure LLC

500 Broadway Street, Suite 480

Vancouver, WA 98660

United States

Issuing Office:

United States

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/ (https://www.cbdpure.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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/ (https://www.cbdpure.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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

[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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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WARNING LETTER

PotNetwork Holdings, Inc.

MARCS-CMS 564030 — 28/03/2019

Product: Drugs
Food & Beverages

Recipient:

Mr. Gary Blum

President

PotNetwork Holdings, Inc.

3531 Griffin Road
Fort Lauderdale, FL 33312
United States

Issuing Office:

Center for Food Safety and Applied Nutrition

5001 Campus Drive
College Park, MD 20740-3835
United States

HHS logo

HHS logo

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 (http://www.diamondcbd.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftn1) 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 (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.

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:

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[1] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftnref1) 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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) 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) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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