

HealthyHempOil.com 2/4/16



Public Health Service
Food and Drug Administration

February 4, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY RETURN RECEIPT REQUESTED

Brandon Nolte
HealthyHempOil.com
Double Minors
823 Congress, Suite 150 #561
Austin, TX 78767

Dear Brandon Nolte:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.healthyhempoil.com in January 2016 and has determined that you take orders there for the products “Herbal Renewals Gold CBD Oil,” “Herbal Renewals CBD Oil Spray,” “Entourage Occam’s Razor Hemp e Liquid,” “Plus CBD Oil Hemp Salve Relief,” and “Hempotion Cannabidiol Extract Tincture,” which you claim contain cannabidiol (CBD). FDA also reviewed your social media websites at <https://twitter.com/healthyhempoil> and <https://www.facebook.com/healthyhempoil/>. The claims on your websites 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/>).

Although you market “Herbal Renewals Gold CBD Oil” and “Herbal Renewals CBD Oil Spray” 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. 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 claims observed on your website www.healthyhempoil.com that establish the intended use of your products include, but may not be limited to, the following:

On the webpage titled “Herbal Renewals: Gold CBD Oil (255mg-15.3g CBD)”:

- “Alleviates anxiety”
- “Strong analgesic properties”
- “CBD has been proven to be effective against inflammation, anxiety and chronic pain.”
- “Studies that are currently underway explore the possibility that CBD is also a powerful natural solution for other serious health problems including symptoms of heart disease, diabetes, cancer”

On the webpage titled “Herbal Renewals: CBD Oil Spray (100mg CBD)”:

- “Introducing the world’s best herbal remedy for anxiety: CBD Spray by Herbal Renewals is here to dissolve your worries away with the powerful, all-natural healing properties of CBD oil.”
- “Herbal Renewals CBD Spray is hailed as the best herbal remedy for anxiety thanks to CBD’s powerful anxiolytic (anti-anxiety) properties.”
- “Cannabidiol has been proven to be a powerful natural remedy against inflammatory diseases, chronic pain, and anxiety without known side effects”
- “[N]ew and emerging research suggests that CBD may also be a potent natural remedy for a wide range of other ailments, including heart disease, . . . diabetes”

On the webpage titled “Entourage: Occam’s Razor Hemp e Liquid (100mg CBD)”:

- “[S]cientific studies have shown potential health benefits for people with:
 - o Anxiety disorders
 - o Inflammation pain
 - o Stress
 - o Nausea”
- “There is also some evidence that CBD may have anti-cancer properties”
- “CBD has also shown promise in diminishing chemotherapy-induced nausea.”

On the webpage titled “Plus CBD Oil: Hemp Salve Relief (50mg CBD)”:

- “Recent scientific studies have showcased CBD’s beneficial effects against inflammation, pain, and anxiety.”
- “Anti-inflammatory”
- “Natural analgesic”

On the webpage titled “Hempotion: Cannabidiol Extract Tincture (100-250mg CBD)”

- “[W]ill alleviate all kinds of anxiety and inflammation problems.”
- “Alleviates anxiety”
- “Strengthens immune system”

On the webpage titled “The Ultimate Resource Page for Cannabidiol (CBD)”:

- “CBD has been shown to be effective for decreasing anxiety and helping in a number of inflammation-related problems, including arthritis and other inflammatory ailments as well as multiple sclerosis.”
- “CBD is also proven to inhibit the growth of the MRSA bacterium (a strain of staphylococcus resistant to antibiotics), which causes several difficult-to-treat infections.”
- “CBD is currently used to treat symptoms of anxiety and certain cases of inflammation.”
- “It has also been shown to be effective in treating a wide range of other ailments. These studies, though still in early stages, imply that CBD could be used to treat . . . multiple sclerosis, and numerous inflammatory diseases, as well as inhibit the growth of certain forms of cancer.”

On the webpage titled “Cannabidiol Anxiety Research”:

- “As many studies show, CBD seems to have anxiolytic properties (inhibits stress and anxiety) without any psychoactive effects, making it a potentially versatile alternative to a number of existing anxiolytic drugs.”

On the webpage titled “Cannabidiol Antipsychotic Research”:

- “CBD seems to have fewer side effects, is more cost effective (when compared to other medications with similar effects), and has been shown to be superior to most conventional antipsychotic medications.”

On the webpage titled “Cannabidiol Cancer Research”:

- “[N]umerous recent studies have verified that cannabidiol exhibits some inhibitory effects on several types of cancer including breast cancer, colon cancer, certain types of brain tumors, leukemia and others.”
- “CBD has been shown to induce programmed cell death in breast cancer cells. . . .”
- “CBD seems to render certain cancerous cells more susceptible to chemotherapy agents.”

On the webpage titled “Cannabidiol Pain Relief Research”:

- “CBD is currently regarded as one of the safest cannabinoids and it has been shown to be effective against a number of cancer-related pains in numerous clinical trials.”
- “CBD and other cannabinoids have also been shown to have effective analgesic properties for terminal cancer patients”

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

<https://twitter.com/healthyhempoil>

- July 14, 2015 posting – “Treating Schizophrenia with Cannabidiol”

<https://www.facebook.com/healthyhempoil/>

- June 5, 2015 posting – “An increasing body of evidence also suggests that cannabidiol, one of the major non-psychoactive cannabinoids in all types of cannabis plants, is a good natural remedy for anxiety.”

Your products “Herbal Renewals Gold CBD Oil,” “Herbal Renewals CBD Oil Spray,” “Entourage Occam’s Razor Hemp e Liquid,” “Plus CBD Oil Hemp Salve Relief,” and “Hempotion Cannabidiol Extract Tincture” 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 “Herbal Renewals Gold CBD Oil,” “Herbal Renewals CBD Oil Spray,” “Entourage Occam’s Razor Hemp e Liquid,” “Plus CBD Oil Hemp Salve Relief,” and “Hempotion Cannabidiol Extract Tincture” 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 Renewals Gold CBD Oil,” “Herbal Renewals CBD Oil Spray,” “Entourage Occam’s Razor Hemp e Liquid,” “Plus CBD Oil Hemp Salve Relief,” and “Hempotion Cannabidiol Extract Tincture” 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 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 be sent to:

U.S. Food and Drug Administration
CDER/OC/OU DLC
10903 New Hampshire Ave, WO51
Silver Spring, MD 20993-0002
FDAADVISORY@fda.hhs.gov

Sincerely,
/S/
Ilisa Bernstein, Pharm.D., J.D.
Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

Cc:

Healthy Hemp Oil
6411 Bella Vista Dr. Ste 1
Rockford, MI 49341

Double Minors LLC
803 Wagonwheel Lane
West Chester, PA 19380

[1] See "Sativex Commences US Phase II/III Clinical Trial in Cancer Pain," available at <http://www.gwpharm.co.uk/Commences%20US%20Phase%20IIIII%20Clinical%20Trial.aspx> 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://www.gwpharm.com/GW%20Pharmaceuticals%20Receives%20Investigational%20New%20Drug%20IND%20from%20FDA%20for%20Phase%2023%20Clinical%20Trial%20of%20Epidiolex%20>

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