Stanley Brothers Social Enterprises, LLC 10/31/17

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 (redirects to www.cwhemp.com) 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, and your social media websites at www.facebook.com/CWHempOfficial and www.twitter.com/CWHemp; these websites direct consumers to your website, www.cwhemp.com, 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 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.**[3]**

Examples of claims observed on www.theroc.us 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 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

- 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

- 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