U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Purecbd.net 2/26/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration

February 26, 2015

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Natural Organic Solutions
Attn: Joe Cain
1001 Cooper Point Rd. SW
Ste.140 #149
Olympia, WA 98502

1675 Mottman Rd. SW
Tumwater, WA 98512

Dear Joe Cain:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the internet address www.purecbd.net and your Etsy.com marketplace store at the internet address www.etsy.com/shop/PureCBD in February 2015, and has determined that you take orders for several products claiming to contain cannabidiol (CBD), such as (but not limited to), “CBD Hemp Oil Treatment,” “Hemp CBD (Cannabidiol) Extract Capsules,” “CBD Extract Capsules Anti Anxiety Formula,” and “High CBD Healing Salve.” FDA also reviewed literature which accompanies the sale and shipment of your products. Based on our review, we have determined that your websites and accompanying literature promote these products for conditions that cause them to be 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, the introduction or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of claims observed in the accompanying literature titled, “Real CBD Cannabis Extracts,” that establish the intended use of your products include, but may not be limited to, the following:

- “It has shown great promise in treating the most aggressive forms of Cancer, MS . . . Resistent [*sic*] Bacteria . . . and so many other conditions.”

- “CBD acts in some experimental models as an anti-inflammatory . . . and antipsychotic agent, and is therefore a potential medicine for the treatment of Neuroinflammation . . . and Schizophrenia, respectively.”

Examples of claims observed on your website www.purecbd.net that establish the intended use of your products include, but may not be limited to, the following:

On the webpage titled, “About”:

- “Our oil is making a difference in the lives of our patients . . . Cancer is going into remission. People are recovering from serious disease.”

On the webpage titled, “Reviews”:

- “CBD hemp oil critical for cancer treatment”

- “Stage 4 Metastatic Breast Cancer Patient has symptom relief”

Examples of claims observed on your www.etsy.com/shop/PureCBD marketplace store website that establish the intended use of your products include, but may not be limited to, the following:

On the webpage titled “30 Capsules CBD Hemp CBD Extract Capsules Anti Anxiety Formula”:

- “CBD Extract Capsules Anti Anxiety Formula”

- “This formula has been specifically designed to prevent Panic/Anxiety Attacks from occurring. The medicine eliminates many of the peaks and valleys that are normally responsible for causing a panic attack.”

On the webpage titled, “4 Ounces High CBD Healing Salve for Wounds, Blemishes and Cancers”:

- “High CBD Healing Salve for Wounds, Blemishes and Cancers”

- “In the pictures above you can see the amazing results. The patient presented with third degree burns. Infection was present. Within 48 hours significant healing has occurred with no sign of infection.”

- “We have treated thousands of patients and have seen this medicine work!”

On the webpage titled, "60 Grams of 26% CBD Hemp Oil Treatment":

- "We have treated hundreds of patients using this methodology. There is no stronger treatment available."

- "Here are a just a few studies using hemp oil to treat various acute disease.

Cancer . . . http://www.ncbi.nlm.nih.gov/pubmed/?term=cbd+cancer
MS . . . http://www.ncbi.nlm.nih.gov/pubmed/?term=cbd+ms
Alzheimer's . . . http://www.ncbi.nlm.nih.gov/pubmed/?term=cbd+Alzheimer's"

It is clear from the claims above that your products, "CBD Hemp Oil Treatment," "Hemp CBD (Cannabidiol) Extract Capsules," "CBD Extract Capsules Anti Anxiety Formula" and "High CBD Healing Salve," are drugs under section 201(g)(1)(B) of the Act.

Moreover, your products "CBD Hemp Oil Treatment," "Hemp CBD (Cannabidiol) Extract Capsules," "CBD Extract Capsules Anti Anxiety Formula" and "High CBD Healing Salve" are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for the use under the conditions prescribed, recommended, or suggested in their labeling. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, your products "CBD Hemp Oil Treatment," "Hemp CBD (Cannabidiol) Extract Capsules," "CBD Extract Capsules Anti Anxiety Formula" and "High CBD Healing Salve" are misbranded within the meaning of section 502(f)(1) of the 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 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 drugs which bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson [21 CFR §§ 201.100(c)(2) and 201.115]. Because "CBD Hemp Oil Treatment," "Hemp CBD (Cannabidiol) Extract Capsules," "CBD Extract Capsules Anti Anxiety Formula" and "High CBD Healing Salve" lack FDA-approved applications, they are not exempt under 21 CFR §§ 201.100(c)(2) and 201.115. For these reasons, these products are misbranded under section 502(f)(1) of the Act. The introduction or delivery for introduction of a misbranded drug into interstate commerce is a violation of 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 and their labeling. 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 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 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 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/OUDLC
10903 New Hampshire Avenue, WO51
Silver Spring, MD 20993-0002
OUDLCMail@fda.hhs.gov (mailto:OUDLCMail@fda.hhs.gov)

Sincerely,

/s/

Cynthia Schnedar, J.D.
Director
Office of Compliance
Center for Drug Evaluation and Research

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)