That's Natural 10/31/17

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine, CA 92612-2506
Telephone: 949-608-2900
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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 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 and at www.twitter.com/PureCBDHempOil; these websites direct consumers to your website, www.cbdoil.life, 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 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

- 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

- 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-iiiii-clinical-trial-cancer-pain; and https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial.
[2] TBI is an abbreviation for traumatic brain injury.

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)