FDA U.S. FOOD & DRUG ADMINISTRATION

United States of America
Federal Trade Commission
Bureau of Consumer Protection
Washington, D.C. 20580

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

October 10, 2019

Mr. Ryan P. Collett
Mr. Cade Copeland
Rooted Apothecary, LLC
3958 Recreation Lane
Naples, FL 34116

4280 Tamiami Trail East
Suite 102
Naples, FL 34112

RE: 585312

Dear Mr. Collett and Mr. Copeland:

This letter is to advise you that the Food and Drug Administration (FDA or Agency) reviewed your website at the Internet address www.rootedapoth.com in July 2019 and has determined that you take orders there for various products that claim to contain cannabidiol (CBD). Your products, "Teeth/TMJ – Essential Oil + CBD Infusion" and "Ears – Essential Oil + CBD Infusion are roll-on products that you sell for topical application in adults and children. Other examples of products that you sell, which claim to contain CBD, include "Hemp Capsules, 750 mg," "Hemp Infused Body Butter," and "Hemp Oil"[1]. On your website, these products are also referred to as "CBD Capsules, 750 mg," "CBD Body Butter," and "CBD Oil," respectively. We also reviewed your social media website at https://www.facebook.com/rootedapoth/, which directs consumers to your website http://www.rootedapoth.com to purchase your products. FDA has determined that your "Teeth/TMJ – Essential Oil + CBD Infusion," "Ears – Essential Oil + CBD Infusion," "Hemp Capsules, 750 mg," "Hemp Infused Body Butter,"

[1] "Hemp Oil" is sold in multiple container amounts including 500 mg, 1000 mg, and 1500 mg.

and "Hemp 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). 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. 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.

As FDA stated in an announcement regarding a warning letter on July 23, 2019, "while we recognize the potential opportunities and significant interest in drug products containing cannabis and cannabis-derived compounds like CBD, protecting and promoting public health remains our top priority."[2] The Agency continues to be concerned about the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses without having been reviewed for safety and effectiveness by the FDA as is required by law and to protect the public health. There are many unanswered questions about the science, safety, effectiveness and quality of unapproved products containing CBD. Without this information, we are unable to ensure that these products will not cause harm to people who use them. With the exception of Dronabinol, Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population.

The Agency is particularly concerned that you market unapproved new drugs for uses in infants and children. Such products include, but are not limited to, "Teeth/TMJ – Essential Oil + CBD Infusion" and "Ears – Essential Oil + CBD Infusion." Your products have not been evaluated by the Agency for safety, effectiveness, and quality. The use of untested drugs can have unpredictable and unintended consequences, especially in vulnerable populations. For example, infants and children may be at greater risk for adverse reactions associated with certain drug products due to differences in the ability of infants and children to absorb, metabolize, distribute, or excrete such drug products or their metabolites.

Dietary Supplement Labeling

In addition, information on your website and social media account indicates that you market your "Hemp Capsules, 750 mg" and "Hemp Oil" products as dietary supplements that contain CBD. However, these products cannot be dietary supplements, because they do not meet the definition of a dietary supplement under section 201(ff) of the FD&C Act, 21 U.S.C. 321(ff). FDA has concluded that, based on available evidence, 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

[2] https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer

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 article 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 the evidence available, FDA has concluded that this is not the case for CBD.[3] 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.[4]

Unapproved New Drug Products

Based on our review of your website, your "Teeth/TMJ – Essential Oil + CBD Infusion," "Ears – Essential Oil + CBD Infusion," "Hemp Capsules, 750 mg," "Hemp Infused Body Butter," and "Hemp 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 intended to affect the structure or any function of the body.

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

On your website www.rootedapoth.com: webpage titled "TEETH/TMJ – Essential Oil + CBD Infusion":

- "Instead of synthetic chemical that can have safety concerns, this blend uses the best of nature to help calm the inflammation and pain of teething, while also promoting sleepiness for your little one."
- "This blend also works great for jaw and TMJ dysfunction pain."
- "Lavender . . . Antidepressant properties."
- "Copaiba – Anti-inflammatory and Analgesic properties . . ."

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[3] 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 and GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome). 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 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.

[4] We also note that your "Hemp Oil" products bear directions for use as sublingual products. The FD&C Act defines the term "dietary supplement" in section 201(ff)(2)(A)(i) of the FD&C Act 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, your "Hemp Oil" products do not meet the definition of a dietary supplement under the FD&C Act for this additional reason.

- "Pain relief . . .."

On your website www.rootedapoth.com: webpage titled "EARS – Essential Oil + CBD Infusion":

- "No matter what age, ear aches are a terrible, no good way to live each day! Our main priority was safety, effectiveness . . . as we formulated this for the entire family including our precious little ones. When the pain is bad, this roller goes to work for soothing pain, inflammation, and to battle against the bacterial/viral critters to blame."
- "Lavender . . . Analgesic, Antibacterial, Sedative . . ."
- "Melaleuca . . . Anti-parasitic, Antiviral . . . Decongestant . . .."

On your website www.rootedapoth.com: webpage titled "CBD Safety: Pregnancy, Breast-Feeding, and Children":

- "Increasing evidence suggests that CBD oil is a powerful option for pain . . . anxiety . . . and autism . . . It seems like an attractive and safe option for children."
- "CBD oil may have neuroprotective properties and may protect against neurological conditions, such as Parkinson's and Alzheimer's disease."
- "CBD oil may improve depression, anxiety, and PTSD."
- "CBD may reduce the risk of cancer or help cancer treatment."
- "CBD may reduce the risk of diabetes."

On your website www.rootedapoth.com: webpage titled "CBD & Kids: Is It Safe?":

- "[P]ossible uses for CBD include helping with skin problems such as acne, autism, ADHD, and even cancer. It's often used in conjunction with traditional treatments to provide extra help. Children can use high amounts of CBD safely and without any risk."

On your website www.rootedapoth.com: webpage titled "What Exactly Does CBD Do?":

- "[R]esearch shows that CBD can have rapid and sustained antidepressant-like effects."

On your Facebook website https://www.facebook.com/pages/rootedapoth/:

- June 13 posting – "Our essential oil & CBD rollers are specifically designed for kiddos & adults. Does your kiddo have teething pain? Try our teething roller!"
- June 5 posting – highlighting a customer review "1500 mg CBD Oil . . . 'I purchased this in anticipation of pain and inflammation following rotator cuff surgery. I am also a type 2 Diabetic. So pleased to see my fasting blood sugars lower since beginning to use the product!!'"

Your "Teeth/TMJ – Essential Oil + CBD Infusion," "Ears – Essential Oil + CBD Infusion," "Hemp Capsules, 750 mg," "Hemp Infused Body Butter," and "Hemp Oil" products are not generally recognized as safe and effective for their above referenced uses; therefore, these 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. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. There are no FDA-approved applications in effect for any of the above-named products.

Misbranded Drug Products

Your 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. (See 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. Under 21 CFR 201.100(c)(2) and 201.115, FDA-approved prescription drugs that 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 because no FDA-approved applications are in effect for them. The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

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 of the FTC via electronic mail at 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.**

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 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 violations may result in legal action without further notice, including, without limitation, seizure and/or 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 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.

Sincerely, Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
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MARY ENGLE

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