Green Roads of Florida LLC 10/31/17

Office of Regulatory Affairs
Office of Human and Animal Food Operations
East Division IV
Compliance Branch
466 Avenida Fernández Juncos
San Juan, Puerto Rico 00901-3223
Tel: (787) 729-8500

October 31, 2017

WARNING LETTER

18-HAFE4-WL-02 / CMS No.513854

VIA UNITED PARCEL SERVICE
NEXT DAY - SIGNATURE REQUIRED

Ms. Laura Fuentes
Greenroads Health
Green Roads of Florida LLC
15757 Pines Blvd., Ste. 178
Pembroke Pines, Florida 33027-1207

Dear Ms. Fuentes:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web site at the Internet address www.Greenroadhealth.com in February 2017, and has determined that you take orders there for the following cannabidiol (CBD) products: “CBD Oil” (100mg, 250mg, 350mg, 550mg), “CBD Tincture” (1000mg and 1500mg), “CBD Oil 100mg + Terpenes Flavor”, “CBD capsules 100mg”, “CBD Crumble 250mg”, “Chamoile Calming Tea” (with CBD), “CBD Edibles Gummie Blocks 60mg”, “CBD Edibles Jollies 30mg”, “CBD Edibles Gummie Men 60mg”, “CBD Edibles Lollypops 30mg”, “CBD Pain Be Gone” Cream 150mg, “CBD Shatter 450mg”, “CBD Dab Wax 250mg”, “CBD Dab Crystal 250mg”, and “CBDreem” (Cannabidiol syrup). The claims on your website 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/)**.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

- “CBD .[has] anti-proliferative properties that inhibit cell division and growth in certain types of cancer, not allowing the tumor to grow.”
- “Almost all studies recognize CBD’s potential in preventing both cancer spread and growth…”
- “The following are some of the many ailments CBD oil can potentially be therapeutic for: asthma, Alzheimer’s disease, arthritis, autism, bipolar disorder, various types of cancer . . .”
- “…considering the lack of risks associated with CBD it is an attractive alternative or addition to anyone’s treatment for Alzheimer’s disease.”
- “Adding CBD oil as part of your daily Alzheimer’s medicine routine has a good chance at delaying the progression of the disease…”
- “[CBD] has antipsychotic properties, which makes it very useful for treating bipolar disorder.”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, these 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 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 “CBD Oil” (100mg, 250mg, 350mg, 550mg), “CBD Tincture” (1000mg and 1500mg), “CBD Oil 100mg + Terpenes Flavor”, “CBD capsules 100mg”, “CBD Crumble 250mg”, “Chamoile Calming Tea” (with CBD), “CBD Edibles Gummie Blocks 60mg”, “CBD Edibles Jollies 30mg”, “CBD Edibles Gummie Men 60mg”, “CBD Edibles Lollypops 30mg”, “CBD Pain Be Gone” Cream 150mg, “CBD Shatter 450mg”, “CBD Dab Wax 250mg”, “CBD Dab Crystal 250mg” and “CBDreem” (Cannabidiol syrup) 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, “CBD Oil” (100mg, 250mg, 350mg, 550mg), “CBD Tincture” (1000mg and 1500mg), “CBD Oil 100mg + Terpenes Flavor”, “CBD capsules 100mg”, “CBD Crumble 250mg”, “Chamoile Calming Tea” (with CBD), “CBD Edibles Gummie Blocks 60mg”, “CBD Edibles Jollies 30mg”, “CBD Edibles Gummie Men 60mg”, “CBD Edibles Lollypops 30mg”, “CBD Pain Be Gone” Cream 150mg, “CBD Shatter 450mg”, “CBD Dab Wax 250mg”, “CBD Dab Crystal 250mg” and “CBDreem” (Cannabidiol syrup) fail to bear adequate directions for their intended use 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)].

Further, it is a prohibited act under section 301(ll) of the Act (21 U.S.C. 331(ll)) to introduce or deliver for introduction into interstate commerce any food to which has been added a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless the drug was marketed in food before any substantial clinical investigations involving the drug were instituted. The existence of substantial clinical investigations regarding CBD has been made public. Based on available evidence, FDA has concluded that section 301(ll) prohibits the introduction into interstate commerce of any food to which CBD

has been added. According to your product labeling, “Chamoile Calming Tea” (with CBD), “CBD Edibles Gummie Blocks 60mg”, “CBD Edibles Jollies 30mg”, “CBD Edibles Gummie Men 60mg”, and “CBD Edibles Lollypops 30mg” are food products which contain cannabidiol (CBD). Therefore, the introduction or delivery for introduction into interstate commerce of those products is a prohibited act under section 301(ll) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for the delay and the date by which each such item will be corrected.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. If you have any questions concerning this letter, please contact Ms. Pearl Gonzalez, Compliance Officer, at (407) 475-4730. Your written response to this letter should be sent to: Ms. Maridalia Torres, District Director, Food and Drug Administration, Office of Human and Animal Food Operations East Division IV, 466 Fernández Juncos Avenue, San Juan, PR 00901-3223.

Sincerely yours,
/S/
Maridalia Torres-Irizarry
Director San Juan District
Program Division Director OHAFO IV East

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