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

Green Garden Gold 2/4/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration

February 4, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY

Justin Barrick
Green Garden Gold, LLC
12400 Coit Road STE 1000
Dallas, TX 75251

Re: 480747

Dear Mr. Barrick:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.GreenGardenGold.com in January 2016 and has determined that you take orders there for the products “Regular CBD-Oil 100mg” and “CBD Strawberry Jam.” We have also reviewed your Facebook page https://www.facebook.com/GreenGardenGold/info?tab=page_info, which provides a link to your website www.GreenGardenGold.com where products can be purchased directly. The claims on these websites establish that your “Regular CBD-Oil 100mg” and “CBD Strawberry Jam” 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 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 claims on your website that provide evidence that your products are intended for use as drugs include the following:

On your home page:

- “Cannibidiol – CBD - is a cannabis compound that has significant medical benefits.”
- “[T]reatment option for patients seeking anti-inflammatory, anti-pain, anti-anxiety, anti-psychotic, and/or anti-spasm effects…”
- “Scientific and clinical studies underscore CBD’s potential as a treatment for a wide range of conditions, including arthritis, diabetes, alcoholism, MS, chronic pain, schizophrenia, PTSD, antibiotic-resistant infections…and other neurological disorders.”
- “[I]ts anti-cancer properties are currently being investigated at several academic research centers in the United States and elsewhere.””

On the webpage titled, “ABOUT US”:

- “[T]here may be extensive potential therapeutic uses of CBD, those being evaluated at Project CBD include Cancer…Anxiety, ADD/ADHD, ALS, Mood Disorders, Heart Disease, sleep disorders….”
- “Potential Therapeutic Uses of Medical Hemp…ADD/ADHD, Addiction, AIDS, ALS, Alzheimer’s… Atherosclerosis, Arthritis, Autism, Bipolar, Cancer, Colitis/Crohn’s, Depression, Diabetes…Fibromyalgia, Glaucoma, Heart disease, Hungtington’s,...Irritable bowel, Kidney disease, Liver disease,…Migraine, Multiple sclerosis…Obesity. OCD, Osteoporosis, Parkinson’s, Prion/Mad Cow disease, PTSD, Rheumatism, Schizophrenia, Sickle cell anemia…Spinal cord injury…Stroke/TB”

Your website also contains evidence of intended use in the form of personal testimonials recommending or describing the use of your CBD products for the cure, mitigation, treatment or prevention of disease. Examples of such testimonials include:

- “The oil…beat other psychiatric medicines out there…It helped stabilize my…anxiety.”
- “I LOVE THIS CBD VAP-OIL!!! I suffer chronic pain…and I have COPD, and lastly…I have diabetes. Some days, I can barely move. My feet and hands look swollen and I feel joint pain. In just a few minutes I feel so much better, and no side effects, like from the pills the VA doctors prescribe.”
- “My wife’s fibromyalgia and anxiety are controlled really well – we use a vape – 3 drags every few hours is all it takes.”
- “After one bottle I am prescription-drug-free, I am moving well, and sleeping well.”
- “CBD is great! I have neuropathy from 44+ years of diabetes and this is the only thing I have found that works.”

Further, claims made on the “About” section of your Facebook page https://www.facebook.com/GreenGardenGold/info?tab=page_info, which includes a link to your website at www.GreenGardenGold.com where products can be purchased directly, provide additional evidence that your products are intended for use as drugs:

- “[P]otential therapeutic uses of medical hemp including ADD/ADHD, AIDS, ALS, Cancer, Mood Disorders, Heart Disease, sleep disorders…”

Your products 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 “Regular CBD-Oil 100mg” and “CBD Strawberry Jam” 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, your “Regular CBD-Oil 100mg” and “CBD Strawberry Jam” products 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 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 these 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 cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

If you need additional information or have questions concerning any products distributed through your website, please contact the FDA. You may respond in writing to Alex Brown at Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740. If you have any questions concerning this letter, please contact Mr. Brown at **FDAADVISORY@fda.hhs.gov (mailto:FDAADVISORY@fda.hhs.gov)**.

Sincerely yours,
/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
Justin Barrick
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More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)