WARNING LETTER

# Nutra Pure LLC

MARCS-CMS 567714 – 28/03/2019

**Product:**

Drugs

**Recipient:**

CJ Montgomery

Nutra Pure LLC

500 Broadway Street, Suite 480

Vancouver, WA 98660

United States

**Issuing Office:**

United States

**WARNING LETTER**

**VIA OVERNIGHT DELIVERY**

**RETURN RECEIPT REQUESTED**

March 28, 2019

CJ Montgomery

Nutra Pure LLC

500 Broadway Street, Suite 480

Vancouver, WA 98660

**RE: 567714**

Dear Mr. Montgomery:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the internet address https://www.cbdpure.com/ (https://www.cbdpure.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in February 2019 and has determined that you take orders there for the products "Hemp Oil" (100mg, 300mg, and 600mg) and "CBD Softgels" which you promote as products containing cannabidiol (CBD). The claims on your website establish that the products are drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (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 because they are intended to affect the structure or any function of the body. 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 (http://www.fda.gov/). In addition, the Federal Trade Commission (FTC) 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.

Although you market "Hemp Oil" and "CBD Softgels" as dietary supplements, FDA has concluded based on available evidence that 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 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.

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**[1]** 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. 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. 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.

Examples of claims observed on your website https://www.cbdpure.com/ (https://www.cbdpure.com/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that establish the intended use of your products as drugs include, but may not be limited to, the following:

On the webpage titled "CBD: Alzheimer's":

- "For Alzheimer's patients, CBD is one treatment option that is slowing the progression of that disease."

- "Science also shows that CBD has anti-emetic, anti-convulsive, anti-inflammatory and analgesic properties. Because all of these come into play with Alzheimer's, particularly brain inflammation, CBD is a viable option for minimizing these effects within the brain."

On a webpage titled "CBD: Anxiety":

- "Cannabidiol (CBD) Treats Neuropsychiatric Disorders"
- "...evidence that the therapeutic efficacy of CBD in the treatment of anxiety-related disorders was pronounced, particularly in the areas of conditioned fear responses, stress, generalized anxiety disorder, social phobia, panic disorder, PTSD, and OCD.
- "CBD can be effective as a treatment in and of itself, or in combination with other treatments."

On the webpage titled "CBD: Depression":

- "For many, CBD holds the answers to treating depression."
- "CBD is a very broad treatment options that targets multiple symptoms and ranges present with depression." [*sic*]

On the webpage titled "CBD: Fibromyalgia":

- "Fibromyalgia is conceived as a central sensitization state with secondary hyperalgesia. CBD has demonstrated the ability to block spinal, peripheral and gastrointestinal mechanisms responsible for the pain associated with migraines, fibromyalgia, IBS and other related disorders."

On the webpage titled "CBD: Skin Conditions":

- "The compounds present in CBD are found to have anti-inflammatory effects . . . Psoriasis is an inflammatory disease"
- "In the study referenced here, CBD was tested specifically in the treatment of psoriasis and found be effective in both stopping the spread of the disease and in alleviating symptoms."
- "...CBD provides a safe, long term option for those suffering from skin disorders."

On your webpage titled "CBD: Inflammation":

- "'Chronic inflammation' [is] when the body is unable to shut off the inflammatory response. This category of inflammation encompasses the following disorders: Rheumatoid arthritis, Psoriatic arthritis, Chron's disease and other inflammatory bowel diseases, Fibromyalgia, Atherosclerosis, Grave's disease, Diabetes, Lupus, Celiac disease . . ."
- "Cannabidiol (CBD) . . . is building a reputation as an effective and safe treatment alternative in the battle against chronic inflammation."

The claims on your websites establish that the 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 because they are intended to affect the structure or any function of the body.

Your products "Hemp Oil" and "CBD Softgels" 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 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, 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 section 502(f)(1) of the FD&C 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 FD&C 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 "Hemp Oil" and "CBD Softgels" 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, "Hemp Oil" and "CBD Softgels" fail to bear adequate directions for their intended uses and, therefore, the products are misbranded under section 502(f)(1) of the FD&C 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 FD&C 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 marketed 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 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 injunction.

**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, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov (mailto: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.

With regard to the FDA-related violations described in this letter, please notify FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps 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 (mailto:FDAADVISORY@fda.hhs.gov).

Sincerely,

/S/

Donald D. Ashley

Director

Office of Compliance

Center for Drug Evaluation and Research

Food and Drug Administration

/S/

Mary K. Engle

Associate Director

Division of Advertising Practices

Federal Trade Commission

[1] See "Sativex Commences US Phase II/III Clinical Trial in Cancer Pain," available at https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain (https://www.gwpharm.com/about/news/sativexr-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and "GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3

Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome," available at http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda (http://ir.gwpharm.com/news-releases/news-release-details/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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