Natural Alchemist 10/31/17

U.S. FOOD & DRUG ADMINISTRATION

Office of Human and Animal Food Division 5 West
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

October 31, 2017

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Natural Alchemist
Alurent, Inc
Attn: Will Claren, CEO
3941 Park Drive
Suite 279
El Dorado Hills, CA 95762

Dear Mr. Will Claren:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.natural-alchemist.com in September 2017 and has determined that you take orders there for the products "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg, and "Natural Alchemist 300mg Hemp Oil drops," all of which you claim contain cannabidiol (CBD). FDA also reviewed your website at the Internet address www.cbd-now.com and determined that you take orders there for the product "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg. Furthermore, www.cbd-now.com directs consumers to purchase Natural Alchemy CBD products online by "[logging] on to the Natural Alchemy CBD website," which we understand to be a reference to www.natural-alchemist.com. The claims on www.cbd-now.com establish that your "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg, and "Natural Alchemist 300mg Hemp Oil drops" products are drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the 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 Act. You can find the Act and FDA regulations through links on FDA's home page at **www.fda.gov (http://www.fda.gov/)**.

Although you market "Natural Alchemist CBD (Cannabidiol) Capsules" 10mg, 25mg, 50mg and "Natural Alchemist 300mg Hemp Oil drops" as dietary supplements, 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.

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

- "Combats tumor and cancer cells"
- "Cannabinoids are found to have particular application . . . in limiting neurological damage following stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease."
- "Study: Cannabinoids a Potential Treatment Option for Chemotherapy-Induced Hearing Loss"
- " [C]annabis plant, enriched with CBD, can be used for treating diseases like rheumatoid arthritis, colitis, liver inflammation, heart disease and diabetes."
- "CBD may have therapeutic benefits in the treatment of various conditions, including . . . rheumatoid arthritis, schizophrenia, diabetes . . . alcoholism, strokes and cardiovascular disease, cancer, and other ailments."
- "People who benefit from cannabidiol: . . . Lupus, L[y]me Disease; Stroke Victims"

Testimonial

- "I was pleasantly surprised to find that CBD helped my arthritis…I have shared with my son and he states he is a big believer in CBD for . . . TBI [traumatic brain injury] after being acquainted with military personnel who have tried it."

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 “Herbal Alchemist CBD (Cannabidiol) Capsules” 10mg, 25mg, 50mg, and “Herbal Alchemist 300mg Hemp Oil drops” 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, “Herbal Alchemist CBD (Cannabidiol) Capsules” 10mg, 25mg, 50mg, and “Herbal Alchemist 300mg Hemp Oil drops” 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)]. 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 assure 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. You may respond in writing to Matthew Walburger, Acting Director of Compliance at 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions concerning this letter, please contact Tammy Hancock, Compliance Officer at 510-337-6737.

Sincerely yours,
/S/
Darla R. Bracy, District Director
Office of Human and Animal Food
Division 5 West

cc:
Natural Alchemist/Alurent Inc.
Attn: Will Claren
3565 South Las Vegas Blvd
Suite 392
Las Vegas, NV 89109

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[1] See “Sativex Commences US Phase II/III Clinical Trial in Cancer Pain,” available at https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain and “GW Pharmaceuticals Receives Investigational