WARNING LETTER

KOI CBD LLC

MARCS-CMS 593391 — NOVEMBER 22, 2019

Delivery Method:

Via Overnight Delivery

Recipient:

Brad Ridenour

KOI CBD LLC

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WARNING LETTER

November 22, 2019

RE: 593391

Dear Mr. Ridenour:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at https://koicbd.com in September 2019 and has determined that you take orders there for the products “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” “KOI CBD Infused Shot” (three varieties), “KOI Naturals CBD Spray for Pets,” and “KOI CBD Soft Chews,” all of which you promote as products containing cannabidiol (CBD). The claims on your website establish that your “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” and “KOI CBD Infused Shot” 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, your products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). FDA has also determined that your "KOI Naturals CBD Spray for Pets" and "KOI CBD Soft Chews" products are unapproved new animal drugs that are unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5).

As explained further below, introducing or delivering these products for introduction into interstate commerce 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. You can find specific information about how FDA regulates CBD at https://www.fda.gov/news-events/public2health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (https://www.fda.gov/news-events/public2 health-focus/fda-regulation-cannabis-and-cannabis-derived-products-includingcannabidiol- cbd).

Dietary Supplement Labeling

Information on your website at https://koicbd.com suggests that you intend to market your "KOI CBD Infused Shot" product as a dietary supplement that contains CBD because the "KOI CBD Infused Shot" is described as a "supplement." However, your product cannot be a dietary supplement because it does 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, 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.***1*** 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. FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary substance definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, but you may present FDA with any evidence bearing on this issue.

Unapproved New Drugs

Based on our review of your website, your "CBD HEALING BALM," "CBD VAPE OIL," "FULL SPECTRUM CBD TINCTURE," "KOI LOTION," "KOI CBD Gummies," and "KOI CBD Infused Shot" 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, https://koicbd.com, that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your webpage titled "8 Proven Benefits of CBD":

- "CBD RELIEVES PAIN AND INFLAMMATION"
- "studies show that CBD prevents human experimental psychosis and is effective in open case reports and clinical trials in patients with schizophrenia, with a remarkable safety profile."

- “Not only does the research show that CBD benefits including being effective in fighting breast cancer cells, data also suggest that it can be used to inhibit the invasion of lung and colon cancer, plus it possesses anti-tumor properties in gliomas and has been used to treat leukemia.”
- “CBD LOWERS INCIDENCE OF DIABETES”

On your webpage titled “IS CBD RIGHT FOR YOU?”:

- “several pre-clinical reports showing anti-tumor effects of CBD…have found reduced [cancer] [sic] cell viability, increased cancer cell death, decreased tumor growth, and inhibition of metastasis.”

On your webpage titled “CBD AND OPIOID ADDICTION”:

- “CBD FOR OPIOID ADDICTION”
- “A potential new treatment for opioid addiction has been found in a new review of previous research of cannabidiol (CBD).”

On your webpage titled “10 LITTLE KNOWN USES FOR CBD”:

- “PTSD”
- “Fibromyalgia”
- “Schizophrenia”
- “Diabetes”
- “MS”
- “Crohn’s Disease”
- “Opioid Addiction”
- “The advantage of cannabidiol as a potential treatment for opioid addiction is that it doesn’t give users a high and thus doesn’t involve a risk of misuse.”

Your “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” and “KOI CBD Infused Shot” 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 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. There are no FDA-approved applications in effect for any of the above mentioned products.

Misbranded Drugs

Your “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” and “KOI CBD Infused Shot” 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.) The aforementioned 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. 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, 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them. 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).

Prohibited Act under 301(ll) and Adulterated Human Foods

We note that your "KOI CBD Gummies" product appears to be promoted as a conventional human food. Specifically, your website refers to the gummies as "delicious, edible CBD snacks." However, you should be aware that it is a prohibited act under section 301(ll) of the FD&C 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 approved under section 505 of the FD&C Act or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Based on available evidence, FDA has concluded that the prohibition in section 301(ll) applies to CBD. There is an exception if the substance was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted. However, based on the available evidence discussed above, FDA has concluded that this is not the case for CBD. FDA is not aware of any evidence that would call into question its current conclusion that section 301(ll) of the FD&C Act prohibits the introduction into interstate commerce of any food to which CBD has been added, but you may present FDA with any evidence bearing on this issue.

You should also be aware that, as defined in section 201(s) of the FD&C Act (21 U.S.C. 321(s)), the term "food additive" refers to any substance the intended use of which results in its becoming a component of any food, unless the substance is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception.**2**

Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe under section 409(a) of the FD&C Act (21 U.S.C. 348(a)), and causes the food to be adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i). Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

There is no food additive regulation which authorizes the use of CBD. We are not aware of any information to indicate that CBD is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that CBD is GRAS for use in conventional foods. FDA's regulations in 21 CFR 170.30(a)-(c) describe the criteria for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific procedures or, for a substance used in food before 1958, through experience based on common use in food (see 21 CFR 170.30).

We know of no basis for general recognition of safety for CBD based either on scientific procedures or common use in food prior to January 1, 1958. Based on our review of published, scientific literature, existing data and information do not provide an adequate basis to conclude that the use of CBD in food meets the criteria for GRAS status. Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. Our review of publicly available data associated with the one FDA-approved CBD drug, as well as our review of published scientific literature, identified potential for liver injury from CBD and potentially harmful interactions with certain drugs. In addition, studies

in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels, and impair sexual behavior in males. Therefore, based on our review, the use of CBD in conventional food products does not satisfy the criteria for GRAS status under 21 CFR 170.30.

FDA is not aware of any other exception to the food additive definition that would apply to CBD for use as an ingredient in a conventional food. Therefore, CBD added to a conventional food is a food additive under section 201(s) of the FD&C Act and is subject to the provisions of section 409 of the FD&C Act. Under section 409, a food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. CBD is not approved for use in any conventional food. Food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i). Therefore, to the extent that you intend to market this products as a food, your "KOI CBD Gummies" product is also adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Introduction of an adulterated food into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Unapproved New Animal Drugs

During our review of your website, https://koicbd.com, FDA determined that your firm is marketing the unapproved new animal drugs "KOI Naturals CBD Spray for Pets" and "KOI CBD Soft Chews." Based on our review of your website, your "KOI Naturals CBD Spray for Pets" and "KOI CBD Soft Chews" 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 in animals and/or intended to affect the structure or any function of the body of an animal. Further, as discussed below, these products are unapproved new animal drugs and marketing them violates the FD&C Act.

Examples of claims observed on your firm's website https://koicbd.com that show the intended uses of these products include, but are not limited to, the following:

On your webpage titled "Is CBD Oil Good for Pets":

- "Do you have a pet who is exhibiting notable discomfort? Consider giving them CBD oil to alleviate their symptoms."
- "So although it helps to alleviate pain, there is no risk of addiction or psychoactive side effects."

These products are "new animal drugs" under section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe
and effective for use under the conditions prescribed, recommended, or suggested in the labeling.

To be legally marketed, a new animal drug must have an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the FD&C Act, 21 U.S.C. 360b, 360ccc, and 360ccc-l. These products are not approved or index listed by the FDA, and therefore these products are considered unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5). Introduction of these adulterated drugs into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

301(ll) and Adulterated Animal Foods

Moreover, to the extent that you market any of your products containing CBD as animal food, you should be aware that it is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), to introduce or deliver for introduction into interstate commerce any animal food to which has been added a drug approved under section 505 of the FD&C Act or for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Based on available evidence, FDA has concluded that the prohibition in section 301(ll) applies to CBD, as described above.

You should also be aware that, as defined in section 201(s) of the FD&C Act (21 U.S.C. 321(s)), the term "food additive" refers to any substance the intended use of which results in its becoming a component of any animal food, unless the substance is generally recognized as safe (GRAS) among qualified experts under the conditions of its intended use, or unless the substance meets a listed exception.***3***

There is no animal food additive regulation that authorizes the use of CBD. We are not aware of any information to indicate that CBD is the subject of a prior sanction (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act). Furthermore, we are not aware of any basis to conclude that CBD is GRAS for use in animal foods. FDA's regulations in 21 CFR 570.30(a)-(c) describe the criteria for eligibility for classification of an animal food ingredient as GRAS. The use of an animal food substance may be GRAS based on either scientific procedures or, for a substance used in animal food before 1958, through experience based on common use in animal food (see 21 CFR 570.30). We know of no basis for general recognition of safety for CBD based either on scientific procedures or common use in animal food prior to January 1, 1958. Based on our review of the publicly available literature, the data and information necessary to support the safe use of CBD in animal foods are lacking. In fact, literature reports have raised safety concerns for animals consuming CBD, including, but not limited to, male reproductive toxicity and liver toxicity. Therefore, based on our review, the use of CBD in animal products does not satisfy the criteria for GRAS status under 21 CFR 570.30.

Under section 409 of the FD&C Act, 21 U.S.C. 348, an animal food additive is deemed unsafe unless it is approved by FDA for its intended use prior to marketing. CBD is not approved for use in any animal food. Animal food containing an unsafe food additive within the meaning of section 409 is adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Introduction of an adulterated animal food into interstate commerce is prohibited under 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, including 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.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct these 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,

/S/
Donald D. Ashley
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

/S/
Eric Nelson
Director of Compliance
Office of Surveilance & Compliance
Center for Veterinary Medicine
Food and Drug Administration

/S/
William A. Correll Jr.
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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1 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 (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.

2 Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food, (2) pesticide chemicals, (3) color additives, (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act), (5) new animal drugs, and (6) dietary ingredients in or intended for use in a dietary supplement.

3 Under section 201(s)(5) of the FD&C Act (21 U.S.C. 321(s)(5)), new animal drugs are excluded from the food additive definition. If a new animal drug is unsafe within the meaning of section 512 because it is not approved for use in animal food, then the animal food is adulterated under section 402(a)(2)(C)(ii) of the FD&C Act.

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