To:	MINDI M. RICHTER(mrichter@shumaker.com)
Subject:	U.S. Trademark Application Serial No. 88588572 - BENEFICIAL BLENDS
Sent:	February 10, 2023 09:55:08 AM EST
Sent As:	tmng.notices@uspto.gov

Attachments

screencapture-www-fda-gov-cosmetics-cosmetics-laws-regulations-it-cosmetic-drug-or-both-or-it-soap-16733892432221
screencapture-www-fda-gov-inspections-compliance-enforcement-and-criminal-investigations-warning-letters-renas-organic-613036-02112022-16733908099091
screencapture-www-fda-gov-inspections-compliance-enforcement-and-criminal-investigations-warning-letters-biomd-plus-llc-618460-05042022-16733908676891
screencapture-www-fda-gov-inspections-compliance-enforcement-and-criminal-investigations-warning-letters-kingdom-harvest-625058-05042022-16733909016151
screencapture-www-fda-gov-news-events-public-health-focus-fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd-16734439211791
screencapture-www-ahdictionary-com-word-search-html-16759827054571
screencapture-chillaxn-com-products-premium-cbd-cream-16759827266951
screencapture-chillaxn-com-products-premium-cbd-roll-on-cream-16760407041981

United States Patent and Trademark Office (USPTO)
Office Action (Official Letter) About Applicant's Trademark Application

U.S. Application Serial No. 88588572

Mark: BENEFICIAL BLENDS

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Applicant: Beneficial Blends LLC

Reference/Docket No. N/A

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REQUEST FOR RECONSIDERATION AFTER FINAL ACTION DENIED

Issue date: February 10, 2023

Applicant's request for reconsideration is denied. *See* 37 C.F.R. §2.63(b)(3). The trademark examining attorney has carefully reviewed applicant's request and determined the request did not: (1)

raise a new issue, (2) resolve all the outstanding issue(s), (3) provide any new or compelling evidence with regard to the outstanding issue(s), or (4) present analysis and arguments that were persuasive or shed new light on the outstanding issue(s). TMEP §§715.03(a)(ii)(B), 715.04(a).

Accordingly, the following requirement(s) and/or refusal(s) made final in the Office action dated July 18, 2022, are **maintained and continued**:

- Section 1 and 45 Refusal – Unlawful Use of the Applied-For Mark in Commerce (FDCA Refusal)
- Specimen Refusal – Substitute Specimen Required

See TMEP §§715.03(a)(ii)(B), 715.04(a).

If applicant has already filed an appeal with the Trademark Trial and Appeal Board, the Board will be notified to resume the appeal. *See* TMEP §715.04(a).

If applicant has not filed an appeal and time remains in the response period for the final Office action, applicant has the remainder of that time to (1) file another request for reconsideration that complies with and/or overcomes any outstanding final requirement(s) and/or refusal(s), and/or (2) file a notice of appeal to the Board. TMEP §715.03(a)(ii)(B).

SECTION 1 AND 45 REFUSAL – UNLAWFUL USE OF THE APPLIED-FOR MARK IN COMMERCE (FDCA REFUSAL)

Registration was previously refused because the applied-for mark was not in lawful use in commerce as of the filing date of the application. Trademark Act Sections 1 and 45, 15 U.S.C. §§1051, 1127; *see* TMEP §907.

To qualify for federal trademark/service mark registration, the use of a mark in commerce must be lawful. *Gray v. Daffy Dan's Bargaintown*, 823 F.2d 522, 526, 3 USPQ2d 1306, 1308 (Fed. Cir. 1987) (stating that "[a] valid application cannot be filed at all for registration of a mark without 'lawful use in commerce'"); TMEP §907; *see In re Stellar Int'l, Inc.*, 159 USPQ 48, 50-51 (TTAB 1968); *Coahoma Chemical Co., Inc. v. Smith*, 113 USPQ 413 (Com'r Pat. & Trademarks 1957) (concluding that "use of a mark in connection with unlawful shipments in interstate commerce is not use of a mark in commerce which the [Office] may recognize."). Thus, the goods and/or services to which the mark is applied must comply with all applicable federal laws. *See In re Brown*, 119 USPQ2d 1350, 1351 (TTAB 2016) (citing *In re Midwest Tennis & Track Co.*, 29 USPQ2d 1386, 1386 n.2 (TTAB 1993) (noting that "[i]t is settled that the Trademark Act's requirement of 'use in commerce,' means a 'lawful use in commerce'")); *In re Pepcom Indus., Inc.*, 192 USPQ 400, 401 (TTAB 1976); TMEP §907.

Cannabidiol (CBD) is a chemical constituent of the cannabis plant. On June 25, 2018, the U.S. Food and Drug Administration (FDA) approved the first prescription pharmaceutical formulation of plant-derived CBD, Epidiolex®, for the treatment of two rare forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. The Drug Enforcement Administration (DEA) placed Epidiolex® on schedule V of the CSA on September 27, 2018. Nevertheless, marijuana and CBD derived from marijuana remain unlawful. No other cannabis-derived drug products have been approved by the FDA. Under the FDCA, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. 21 U.S.C. § 321(g)(1). An unapproved new drug cannot be distributed or sold in interstate commerce

unless it is the subject of an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA). 21 U.S.C. §§ 331(d) and 355(a), (b), & (j); *see also FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers copy previously attached.

Here, the goods to which the proposed mark are applied are unlawful under the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §321(g)(1). Though applicant identifies its goods as "Skin lotions and oils for cosmetic purposes; any CBD in the goods being solely derived from hemp with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis" evidence of record and the applicant's specimen contradict the cosmetic nature of this identification.

Applicant concedes that its "products are for help in relieving tension and inflammation."

The applicant then argues that its products are also for "better looking skin and are meant not for those who are sick or have a disease but rather for those with an athletic and/or active lifestyle. The goods at issue are very simply not a drug, and the FDA has made clear that topical products such as this helping inflammation caused by exercise or an active lifestyle are excepted from being defined as a drug and do not require FDA approval." The applicant provides additional arguments with attached evidence that the FDA does not regulate over the counter (OTC) products intended to be used as topical products for helping inflammation.

The applicant further argues "[t]he FDA, not the USPTO, is the government body that determines what products are considered drugs and/or for medical use such that they require FDA approval, and the FDA does not require approval for products like those of Applicant."

These arguments have been considered and found unpersuasive.

The FDA treats goods with CBD as an active ingredient differently from other drugs and OTC products. Specifically, any product intended to have a therapeutic or medicinal use containing CBD is considered a drug, and the FDA does not include CBD as an acceptable ingredient in OTC goods. "We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses, and we have issued several warning letters to such firms. **Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug**. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. **CBD was not an ingredient considered under the OTC drug review**. An unapproved new drug cannot be distributed or sold in interstate commerce." (emphasis added). *See* previously attached *FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers.* However, for applicant's convenience, the examining attorney has reattached the referenced FDA webpage with the referenced quotation highlighted.

The attached webpage from the FDA entitled "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)," provides the difference between "cosmetics" and "drugs" as well as provides explanations on how to determine a products intended use. The following is an example provided by the FDA of determining intended use of a product, "a massage oil that is simply intended to lubricate the skin and impart fragrance is a cosmetic, but if the product is intended for a therapeutic use, such as relieving muscle pain, it's a drug." *See* attached website screenshots. As such, the manner in which the applicant's goods

are advertised and marketed to consumers, such as stating "Oil up your achy joints for inst-ahhh relief; Rejuvenate with sooothing relaxation; Puts inflammation on notice so you can stay active; Melt away soreness & tension" establishes that the goods are therapeutic in nature. *See* attached website screenshots from applicant's website.

As discussed above the FDA treats products used for relieving pain and inflammation as therapeutic goods and as a drug. To further support this determination that topical products intended to relieve aches, pain, and inflammation are in violation of the FDCA, please see the attached FDA Warning Letters sent to Rena's Organic, BioMD Plus LLC, and Kingdom Harvest, which reference reviewing the applicant's website and marketing materials to determine the intended use of the associated products. The following excerpts from the attached warning letters have been provided (emphasis added):

- The letter to Rena's Organic states:

  This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.renasorganic.com in February 2022 and has determined that you take orders there for the products..."500 mg Pain Relief Cream," "1000 mg Pain Relief Cream,"...all of which you promote as products containing cannabidiol (CBD). We have also reviewed your social media websites at www.facebook.com/RenasOrganic and www.instagram.com/renasorganic; these websites direct consumers to your website, www.renasorganics.com to purchase your products. **The claims on your website and social media websites establish that your..."500 mg Pain Relief Cream," "1000 mg Pain Relief Cream,"...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)**..."500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" are external analgesic drug products subject to section 505G of the FD&C Act, 21 U.S.C. 355h, which governs nonprescription drugs marketed without an approved application. Under section 505G of the FD&C Act, certain nonprescription drugs without an approved application —commonly referred to as "OTC monograph drugs"—may be legally marketed if they meet applicable requirements. In particular, topical products intended for use as an external analgesic are deemed to be GRASE and not a "new drug" if, among other things, they conform to the tentative final monograph (TFM) that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330...**However, your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products do not conform to the conditions of use specified in the final administrative order, because the products' active ingredient, CBD, is not an active ingredient in such order (nor in any applicable final monograph or TFM)**. (emphasis added).

- The letter to BioMD states:

  This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at www.biomdplus.com in February 2022 and has determined that you take orders there for various human and animal products, which you represent as containing cannabidiol (CBD) or Delta-8 tetrahydrocannabinol (THC). We have also reviewed your social media websites at https://twitter.com/bioMDplus, https://www.facebook.com/bioMDplus/ and https://www.instagram.com/biomdplus/, which direct consumers to your website www.biomdplus.com to purchase your products.

The claims on your website and social media accounts establish that your products, some of which are available in multiple varieties...**"CBD Pain Relief Cream,"**...(hereinafter referred to as "your CBD and Delta-8 THC products for humans") are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d)...On your CBD Pain Relief Cream webpage: "bioMDplus Pain Cream in 500mg strength is a new formulated pain relief **topical cream that made for use on sore muscle areas and areas where there is pain**. bioMDplus Pain Cream infused with the Quality Full Spectrum CBD. bioMDplus CBD Cream provides effective, fast and long-lasting pain relief."...Based on the above labeling claims, your CBD and Delta-8 THC products for human use are drugs. We are not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that any of these products are generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended or suggested in their labeling. Thus, your CBD and Delta-8 THC products for human use are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p)...**Even if your "CBD Pain Relief Cream" was considered a nonprescription drug, we note that a nonprescription drug product containing CBD cannot be legally marketed without an approved new drug application**, regardless of whether the CBD is represented on the labeling as an active ingredient or an inactive ingredient. To date, no CBD-containing drug has met applicable FDA requirements to be legally marketed for nonprescription use. **Nonprescription drug products that include CBD as an active ingredient are not GRASE and are new drugs which require an approved application to be legally marketed**. (emphasis added).

- The letter to Kingdom Harvest states:

  This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.kingdomharvest.com from October 2021 through April 2022 and has determined that you take orders there for various human and animal products, which you represent as containing cannabidiol (CBD) or Delta-8 tetrahydrocannabinol (THC). We have also reviewed your social media websites at https://www.facebook.com/originalkingdomharvest/ and https://www.instagram.com/kingdomharvest/?hl=en; which direct consumers to your website www.kingdomharvest.com to purchase your products. The claims on your website and social media accounts establish that your products, some of which are available in multiple varieties...**"Pain Relieving CBD Cream," "Pain Relieving Cream," "CBD & Menthol Pain Freeze Roll-On,"**...(hereinafter referred to as "your CBD and Delta-8 THC products for humans"), 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)...Even if your "Pain Relieving CBD Cream," "Pain Relieving Cream," "CBD & Menthol Pain Freeze Roll-On,"...products were considered nonprescription drugs, we note that a nonprescription drug product containing CBD cannot be legally marketed without an approved new drug application, regardless of whether the CBD is represented on the labeling as an active ingredient or an inactive ingredient. To date, no CBD-containing drug has met applicable FDA requirements to be legally marketed for nonprescription use. Nonprescription drug products that include CBD as an active ingredient are not GRASE and are new drugs which require an approved application to be legally marketed. CBD is not an active ingredient in any OTC monograph under section 505G of the FD&C Act. **Even if CBD could be considered an inactive ingredient in a**

> **nonprescription drug product, that product would still need an approved new drug application to be legally marketed, because the product would not meet the general requirements under section 505G of the FD&C Act under which certain nonprescription drug products may be marketed without an approved new drug application.** In particular, such a product would not meet the general requirement with respect to the safety and suitability of inactive ingredients under 21 CFR 330.1(e).(emphasis added).

Lastly, the applicant argues that the applicant's specimen states "what's more, our topicals rejuvenate the skin, too." and that the applicant's goods are cosmetic in nature. To note the attached website screenshots from the applicant's website do not describe the products as being used to "rejuvenate the skin." Moreover, the applicant's website and specimen of use indicate that the identified good are intended to have a therapeutic use for the alleviation and treatment of inflammation and aches. It is this intended use which ultimately violates the FDCA, as explained in greater detail above with extensive examples from the FDA. The attached and referenced FDA warning letters establish that a review of an applicant's website and social media pages is a legitimate means to determine an intended use of the associated goods. Ultimately, the conflict between the applicant's identification of with the applicant's website and specimen providing that the intended use is for therapeutic pain relief purposes, is the reason for the FDCA Refusal and Specimen Refusal.

New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in 21 U.S.C. §§331(d) and 355(a). In order for an application to have a valid basis that could properly result in a registration, the use of the mark has to be lawful. *See In re Pepcom Indus., Inc.*, 192 USPQ 400, 401 (TTAB 1976). The claimed use of the mark in commerce without FDA approval would be unlawful use in commerce.

In the event applicant is currently seeking FDA approval of the marketing of its goods, applicant may submit a copy of its marketing application and amend the filing basis of the application to claim a bona fide intent to use the mark in commerce under Section 1(b), 15 U.S.C. §1051(b), until such time as applicant's application is approved, and lawful use may be alleged. *See* 37 C.F.R. §§2.34 *et seq*., TMEP §§806 *et seq*. Alternatively, applicant may respond to the stated refusal by submitting evidence and arguments against the refusal.

Ultimately, because the applicant's goods contain CBD the goods are treated differently from other OTC medicines by the FDA, which prohibits use of CBD in said goods.

For these reasons, the FDCA Refusal under Section 1 and 45 is now made FINAL.

SPECIMEN REFUSAL - DOES NOT SHOW USE WITH IDENTIFIED GOODS

Applicant was previously refused registration in International Class 003 because the specimen of record did not show use with the identified non-medicated skincare products. Response options for overcoming that refusal, if any, were set forth in the prior Office action. Applicant responded by arguing against the specimen refusal; however, the arguments have been considered and found unpersuasive for the reasons immediately stated below.

The applicant has applied-for the mark **BENEFICIAL BLENDS** for use in connection with "Skin lotions and oils for cosmetic purposes; any CBD in the goods being solely derived from hemp with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis"

in International Class 003.

The applicant's current specimen of record makes clear that the goods depicted therein are therapeutic or medicinal topical products, as explained in greater detail above. The TMEP states "[w]hen a specimen discloses that use of the identified goods is limited to a particular function or purpose, classification may be impacted." The TMEP goes on to provide the following example "orthopedic shoes are classified in Class 10 as medical apparatus, and ordinary shoes are classified in Class 25. If the specimen in an application for "shoes" in Class 25 shows that the goods are orthopedic shoes, the identification and classification must be amended to "orthopedic shoes" in Class 10." *See* TMEP §1401.07. Similar to the example provided in the TMEP, the specimen of use and attached website screenshots from applicant's website clearly establish that the goods are intended to be used for therapeutic or medicinal purposes to relieve inflammation and alleviate aches.

Applicant argues the specimen of use does state "what's more, our topicals rejuvenate the skin, too." This phrase appears to convey an incidental benefit of the applicant's medicinal products rather than the intended use of applicant's goods. Moreover, "topicals" are defined as "Medicine Relating to, applied to, or affecting a localized area of the body, especially of the skin: a topical anesthetic." *See* attached American Heritage Dictionary definition. Medicinal and therapeutic goods are properly classified in International Class 005 with "pharmaceuticals" rather than the current classification in International Class 003, which is intended for "cosmetics and cleaning preparations." *See* TMEP §1401. Accordingly, this refusal is made final because the specimen of record demonstrates use with goods in International Class 005 rather than the identified goods in International Class 003.

Examples of specimens. Specimens for goods include a photograph of (1) the actual goods bearing the mark; (2) an actual container, packaging, tag or label for the goods bearing the mark; or (3) a point-of-sale display showing the mark directly associated with the goods. *See* 37 C.F.R. §2.56(b)(1), (c); TMEP §904.03(a)-(m). A webpage specimen submitted as a display associated with the goods must show the mark in association with a picture or textual description of the goods and include information necessary for ordering the goods. TMEP §904.03(i); *see* 37 C.F.R. §2.56(b)(1), (c).

Any webpage printout or screenshot submitted as a specimen must include the webpage's URL and the date it was accessed or printed on the specimen itself, within the TEAS form that submits the specimen, or in a verified statement under 37 C.F.R. §2.20 or 28 U.S.C. §1746 in a later-filed response. *See* 37 C.F.R. §2.56(c); TMEP §§904.03(i), 1301.04(a).

Response option. Applicant may respond to this refusal by submitting, for each applicable international class, a different specimen (a verified "substitute" specimen) that (a) was in actual use in commerce prior to the expiration of the deadline for filing the statement of use and (b) shows the mark in actual use in commerce for the goods and/or services identified in the statement of use. A "verified substitute specimen" is a specimen that is accompanied by the following statement made in a signed affidavit or supported by a declaration under 37 C.F.R. §2.20: "The substitute (or new, or originally submitted, if appropriate) specimen(s) was/were in use in commerce prior to expiration of the filing deadline for filing a statement of use." The substitute specimen cannot be accepted without this statement.

Applicant may not withdraw the statement of use. *See* 37 C.F.R. §2.88(f); TMEP §1109.17.

For an overview of this response option and instructions on how to submit a different specimen using the online Trademark Electronic Application System (TEAS) form, see the Specimen webpage.

COMMENTS

Applicant may call or email the assigned trademark examining attorney with questions about this Office action. Although an examining attorney cannot provide legal advice, the examining attorney can provide additional explanation about the refusal(s) and/or requirement(s) in this Office action. *See* TMEP §§705.02, 709.06.

The USPTO does not accept emails as responses to Office actions; however, emails can be used for informal communications and are included in the application record. *See* 37 C.F.R. §§2.62(c), 2.191; TMEP §§304.01-.02, 709.04-.05.

How to respond. File a **request form for reconsideration of this final Office action** that fully resolves all outstanding requirements and/or refusals and/or file a timely **appeal form to the Trademark Trial and Appeal Board** with the required fee(s). Alternatively, applicant may file a **request form for an extension of time to file a response** for a fee.

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Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)

NOTE on antibacterial soaps: For the latest information, see *FDA issues final rule on safety and effectiveness of antibacterial soaps*.

Available in:

- Spanish, PDF: 183KB
- French, PDF: 194KB
- Simplified Chinese: PDF 251KB
- Traditional Chinese, PDF: 260KB
- Korean, PDF: 217KB

Whether a product is a cosmetic or a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. Firms sometimes violate the law by marketing a cosmetic with a drug claim or by marketing a drug as if it were a cosmetic, without adhering to requirements for drugs.

Content current as of:
02/25/2022

Regulated Product(s)
Cosmetics

How does the law define a cosmetic?

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product.

How does the law define a drug?

The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

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How can a product be both a cosmetic and a drug?

Some products meet the definitions of both cosmetics and drugs. This may happen when a product has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

What about "cosmeceuticals"?

The FD&C Act does not recognize any such category as "cosmeceuticals." A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law.

How is a product's intended use established?

Intended use may be established in a number of ways. The following are some examples:

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- Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, increase or decrease the production of melanin (pigment) in the skin, or regenerate cells.
- Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do.
- Ingredients that cause a product to be considered a drug because they have a well-known (to the public and industry) therapeutic use. An example is fluoride in toothpaste.

This principle also holds true for "essential oils." For example, a fragrance marketed for promoting attractiveness is a cosmetic. But a fragrance marketed with certain "aromatherapy" claims, such as assertions that the scent will help the consumer sleep or quit smoking, meets the definition of a drug because of its intended use. Similarly, a massage oil that is simply intended to lubricate the skin and impart fragrance is a cosmetic, but if the product is intended for a therapeutic use, such as relieving muscle pain, it's a drug.

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How are the laws and regulations different for cosmetics and drugs?

The following information is not a complete treatment of cosmetic or drug laws and regulations. It is intended only to alert you to some important differences between the laws and regulations for cosmetics and drugs in the areas of approval, good manufacturing practice, registration, and labeling. Questions regarding laws and regulations for drugs should be directed to FDA's Center for Drug Evaluation and Research (CDER).

How are approval requirements different?

Under the FD&C Act, cosmetic products and ingredients, with the exception of color additives, do not require FDA approval before they go on the market. Drugs, however, must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. These monographs specify conditions whereby OTC drug ingredients are generally recognized as safe and effective, and not misbranded. Certain OTC drugs may remain on the market without an NDA approval until a monograph for its class of drugs is finalized as a regulation. However, once FDA has made a final determination on the status of an OTC drug category, such products must either be the subject of an approved **NDA** [FD&C Act, sec. 505(a) and (b)], or comply with the appropriate **monograph** for an OTC drug. (**A note on the term "new drug":** Despite the word "new," a "new drug" may have been in use for many years.

If a product is intended for use as a drug, it must comply with the requirements outlined above.)

What do these terms mean?

- An **NDA** is the vehicle through which drug sponsors formally propose that FDA approve a pharmaceutical for sale and marketing in the United States. FDA only approves an NDA after determining, for example, that the data is adequate to show the drug's safety and effectiveness for its proposed use and that its benefits outweigh the risks. The NDA system is also used for new ingredients and for new indications entering the OTC marketplace for the first time. For example, the newer OTC products (previously available only by prescription) are first approved through the NDA system, and their "switch" to OTC status is then approved, also through the NDA system.
- FDA has published **monographs**, or rules, for a number of OTC drug categories. These monographs, which are published in the Federal Register, state requirements for categories of nonprescription drugs, such as what ingredients may be used and for what intended use. Among the many nonprescription drug categories covered by OTC monographs are
    - acne medications
    - treatments for dandruff, seborrheic dermatitis, and psoriasis
    - sunscreens

You can find information on FDA's website, under "Development and Approval Process (Drugs)," especially "How Drugs Are Developed and Approved." If you still have questions about NDAs and OTC monographs, or any other aspect of drug regulation, please contact CDER. You can contact CDER's Division of Drug Information, Small Business Assistance at CDERSmallBusiness@fda.hhs.gov or, for general drug-related inquiries, CDER's Division of Drug Information at druginfo@fda.hhs.gov.

How are good manufacturing practice requirements different?

Good manufacturing practice (GMP) is an important factor in helping to assure that your cosmetic products are neither adulterated nor misbranded. However, while FDA has provided guidelines for cosmetic GMP (see "Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist"), no regulations set forth specific GMP requirements for cosmetics. In contrast, the law requires strict adherence to GMP requirements for drugs, and there are regulations specifying minimum current GMP requirements for drugs [Title 21 of the Code of Federal Regulations (CFR), parts 210 and 211]. Failure to follow GMP requirements causes a drug to be adulterated [FD&C Act, sec. 501(a)(2)(B)].

How are registration requirements different?

FDA maintains the Voluntary Cosmetic Registration Program, or VCRP, for cosmetic establishments and formulations [21 CFR 710 and 720]. As its name indicates, this program is voluntary. The FD&C Act does not require cosmetic firms to register their

establishments or list their product formulations with FDA. In contrast, it is mandatory for drug firms to register their establishments and list their drug products with FDA [FD&C Act, sec. 510; 21 CFR 207]. See Drug Registration and Listing System (DRLS and eDRLS).

How are labeling requirements different?

A cosmetic product must be labeled according to cosmetic labeling regulations. See the Cosmetic Labeling Manual for guidance on cosmetic labeling and links to the regulations related to cosmetic labeling. OTC drugs must be labeled according to OTC drug regulations, including the "Drug Facts" labeling, as described in 21 CFR 201.66 Combination OTC drug/cosmetic products must have combination OTC drug/cosmetic labeling. For example, the drug ingredients must be listed alphabetically as "Active Ingredients," followed by cosmetic ingredients, listed in descending order of predominance as "Inactive Ingredients."

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And what if it's "soap"?

Soap is a category that needs special explanation. That's because the regulatory definition of "soap" is different from the way in which people commonly use the word. Products that meet the definition of "soap" are exempt from the provisions of the FD&C Act because—even though Section 201(i)(1) of the act includes "articles...for cleansing" in the definition of a cosmetic—Section 201(i)(2) excludes soap from the definition of a cosmetic.

How does FDA define "soap"?

Not every product marketed as soap meets FDA's definition of the term. FDA interprets the term "soap" to apply only when

- the bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product's detergent properties are due to the alkali-fatty acid compounds, and
- the product is labeled, sold, and represented solely as soap [21 CFR 701.20].

Products that meet this definition of soap are regulated by the Consumer Product Safety Commission (CPSC), not by FDA. Please direct questions about these products, such as safety and labeling requirements, to CPSC.

If a cleanser does not meet all of these criteria...

If a product intended to cleanse the human body does not meet all the criteria for soap, as listed above, it is either a cosmetic or a drug. For example:

If a product

- consists of detergents, or
- primarily of alkali salts of fatty acids, and
- is intended not only for cleansing but also for other cosmetic uses,

it is regulated as a cosmetic. Examples of cosmetic uses include making the user more attractive, by acting as a deodorant, imparting fragrance to the user, or moisturizing the skin.

If a product

- consists of detergents, or
- primarily of alkali salts of fatty acids, and
- is intended not only for cleansing but also to cure, treat, or prevent disease, or to affect the structure or any function of the human body,

it is regulated as a drug, or possibly both a drug and a cosmetic. Examples include antibacterial cleansers and cleansers that are also intended to treat acne.

If a product

- is intended solely for cleansing the human body,
- has the characteristics consumers generally associate with soap, and
- does not consist primarily of alkali salts of fatty acids,

it may be identified in labeling as soap, but it is regulated as a cosmetic.

Resources

- Aromatherapy
- CDER-CFSAN Agreement on Products with Drug Claims Marketed as Cosmetics
- Cosmeceutical
- Antibacterial Soap? You Can Skip It. Use Plain Soap and Water
- Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND (PDF - 305KB)
- Import Alert #66-41: Detention Without Physical Examination of Unapproved New Drugs Promoted In the United States
- Frequently Asked Questions on Soap
- Thigh Creams (Cellulite Treatments)
- Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics
- Wrinkle Treatments and Other Anti-aging Products

WARNING LETTER

Rena's Organic

MARCS-CMS 613036 – FEBRUARY 11, 2022

More Warning Letters

Warning Letters

About Warning and Close-Out Letters

Delivery Method: Via Email

Product: Dietary Supplements
Drugs
Food & Beverages

Recipient:
Ms. Rena S. Greenberg
Registered Agent
Rena's Organic
414 26th St West
Bradenton, FL 34205-4926
United States

SUPPORT@renasorganic.com

Issuing Office:
Office of Human and Animal Food Operations East
Division IV
United States

Content current as of:
05/03/2022

Regulated Product(s)
Dietary Supplements
Drugs
Food & Beverages

WARNING LETTER

22-HAFE4-WL-02/CMS No. 613036

Dear Ms. Greenberg:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.renasorganic.com in February 2022 and has determined that you take orders there for the products "300 mg CBD Full Spectrum Oil

Cannabinoid Tincture", "600 mg CBD Full Spectrum Oil Cannabinoid Tincture," "1500 mg CBD Full Spectrum Oil Cannabinoid Tincture," "500 mg Pain Relief Cream," "1000 mg Pain Relief Cream," "1000 mg CBD Anti-Aging Beauty Cream," "CBD Super Cider," "CBD Super Food," and "Rena's Organic For Pets 300mg CBD," all of which you promote as products containing cannabidiol (CBD). We have also reviewed your social media websites at www.facebook.com/RenasOrganic and www.instagram.com/renasorganic; these websites direct consumers to your website, www.renasorganics.com to purchase your products. The claims on your website and social media websites establish that your "300 mg CBD Full Spectrum Oil Cannabinoid Tincture," "600 mg CBD Full Spectrum Oil Cannabinoid Tincture," "1500 mg CBD Full Spectrum Oil Cannabinoid Tincture," "500 mg Pain Relief Cream," "1000 mg Pain Relief Cream," "1000 mg CBD Anti-Aging Beauty Cream," "CBD Super Cider," and "CBD Super Food" 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, these 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 "Rena's Organic For Pets 300mg CBD" product is an unapproved new animal drug that is 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/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

Unapproved New Human Drugs

Based on our review of your website and your social media websites, your "300 mg CBD Full Spectrum Oil Cannabinoid Tincture," "600 mg CBD Full Spectrum Oil Cannabinoid Tincture," "1500 mg CBD Full Spectrum Oil Cannabinoid Tincture," "500 mg Pain Relief Cream," "1000 mg Pain Relief Cream," "1000 mg CBD Anti-Aging Beauty Cream," "CBD Super Cider," and "CBD Super Food" 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://renasorganic.com and your social media website https://www.facebook.com/RenasOrganic/ that establish the intended use of your products as drugs include, but may not be limited to, the following:

On the Blog post, "3 Reasons to Be Excited About CBD!" dated January 15, 2021:
- "Cancer-Fighting Capabilities . . . recent studies have shown that CBD can act as a direct antitumor agent for a variety of aggressive cancers and can even prevent the spread of cancer cells in the body."
- "Potential for Neurodegenerative Disorders and Brain Injury . . . CBD has various

neuroprotective effects that have shown effectiveness against neural cell damage related to various neurodegenerative disorders such as Alzheimer's. CBD consumption can limit or prevent the damage caused by the advancing disease and even slow down the progression of degenerative brain diseases. Studies are also being conducted to conclusively prove the benefit of administering CBD immediately after traumatic brain injuries or spinal cord injuries to prevent the release of harmful mediators that often lead to permanent brain damage in such scenarios."

On the webpage titled, "CBD Oil: Can It Treat Opioid Dependency?" linked from your Facebook post dated October 10, 2020 (which states "Opioid addiction kills 130 people in the USA every day. The medical community believes that CBD can curb opioid dependence in the country."):

• "CBD is being touted as a safer alternative to opioids in the market. Unlike opioids, CBD isn't addictive and doesn't have psychoactive properties. Preliminary studies show that CBD can reduce opioid cravings, and that it breaks the addiction cycle."

• "Seeing how CBD effectively manages pain, many healthcare providers have started recommending it to patients suffering from chronic pain and undergoing chemotherapy."

• "Prevents Relapse . . . According to preclinical studies, the therapeutic properties of CBD can reduce cravings for psychostimulants, opioids and hard drugs like cocaine. CBD also rewires the brain's programming to lower the intensity of cravings, making it easier to break the opioid addiction."

On the Blog post, "How CBD Can Help You Quit Smoking" dated August 27, 2020:

• "CBD can help you with smoking cessation. There's mounting evidence that suggests that CBD can decrease the urge to smoke, until it disappears altogether."

• "According to studies, CBD oil can help weaken habitual triggers and breaks the addictive association with time, allowing smokers to quit."

• "Preventing Relapse . . . While there still isn't enough research to confidently say that CBD oil can eliminate nicotine addiction, ongoing studies have proven that it can be used to prevent relapses when quitting cocaine and morphine."

• "Combating Nicotine Withdrawal . . . CBD triggers the release of serotonin by reacting with 5-HT1A receptors in the brain (just like antidepressants) and prevents anxiety, stress and moodiness caused by quitting smoking."

On the webpage titled, "CBD Oil: Can it Help ADHD Patients?" linked from your Facebook post dated October 23, 2020:

• "CBD is especially useful in releasing serotonin in the body to combat feelings of anxiety and stress. Increased levels of serotonin in the body help us feel more relaxed and boost concentration—this is why many patients believe CBD can treat ADHD."

• "CBD is a much safer alternative to conventional ADHD treatment. It's all-natural, and it reacts with our bodies inbuilt receptors to promote optimal functionality."

receptors with our bodies innate receptors to promote optimal functionality."

On the webpage titled, "Curing Insomnia with CBD" linked from your Facebook post dated October 24, 2020:

• "Anxiety and insomnia go hand in hand. People who suffer from anxiety usually struggle with insomnia. Treating anxiety through therapy, medication, or CBD can help people sleep better."

On the webpage titled, "What is CBD?":

• "At Rena's Organic, I want you to share with you the truth about CBD and its amazing properties. That's because I want you and your loved ones to have an alternative to risky and debilitating pills and opioids."

On the Blog post, "How to Use CBD to Combat Holiday Stress" dated January 22, 2021:

• "Reduced Anxiety and Depression . . . Studies show that cannabidiol has anxiolytic-like and anti-depressant-like effects, which can help reduce anxiety and depression in many people. While more research is required to prove the therapeutic effects of CBD, there are several studies that suggest that CBD can help alleviate some symptoms of depression and make the condition easier to manage."

On the webpage titled, "Using CBD Oil for the Symptoms of Fibromyalgia" linked from your Facebook post dated February 9, 2021:

• "CBD oil has helped countless patients gain relief from the debilitating symptoms of fibromyalgia."

• "According to a 2020 review, CBD oil has proven to . . . reduce inflammation, and relieve chronic pain. CBD also helps with . . . anxiety, which can keep people from achieving a state of complete rest."

On the product page for "CBD Super Cider":

• "Curbs Cravings"

• "Helichrysum [an ingredient in CBD Super Cider] is a powerful compound that works on your Endo-cannabinoid system. It is know [sic] to be a potent:
  o Anti-depressant
  o Mood stabilizer
  o Inflammation Fighter"

• "Orange Essential Oil [an ingredient in CBD Super Cider] may naturally relieve anxiety, . . . depression and inflammation of the body."

Your "300 mg CBD Full Spectrum Oil Cannabinoid Tincture," "600 mg CBD Full Spectrum Oil Cannabinoid Tincture," "1500 mg CBD Full Spectrum Oil Cannabinoid Tincture," "1000 mg CBD Anti-Aging Beauty Cream," "CBD Super Cider," and "CBD Super Food" are not generally recognized as safe and effective for the above referenced uses and, therefore, the

therefore, these products are "new drugs" under section 201(p) of the Act [21 U.S.C. 321(p)]. With certain exceptions not applicable here, 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.

External Analgesic Drug Products

Based on the above labeling claims, "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" are topical products intended for use as external analgesics, among other uses. As described below, these external analgesic drug products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

As previously noted, in general, a drug product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), if it is not GRASE for use under the conditions prescribed, recommended, or suggested in its labeling; and in general, new drugs may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in section 505(a) of the FD&C Act, 21 U.S.C. 355(a). No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" drug products.

"500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" are external analgesic drug products subject to section 505G of the FD&C Act, 21 U.S.C. 355h, which governs nonprescription drugs marketed without an approved application. Under section 505G of the FD&C Act, certain nonprescription drugs without an approved application — commonly referred to as "OTC monograph drugs"—may be legally marketed if they meet applicable requirements. In particular, topical products intended for use as an external analgesic are deemed to be GRASE and not a "new drug" if, among other things, they conform to the tentative final monograph (TFM) that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330. We note that OTC topical external analgesic products were addressed in the TFM for External Analgesic Drug Products for Over-the-Counter Human Use (external analgesic TFM; 48 FR 5852, February 8, 1983) and subsequent rulemakings. The 1983 external analgesic TFM, in combination with subsequent determinations, was deemed to be a final administrative order by section 505G(b)(8) of the FD&C Act. However, your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products do not conform to the conditions of use specified in the final administrative order, because the products' active ingredient, CBD, is not an active ingredient in such order (nor in any applicable final monograph or TFM).

Although CBD is listed as an inactive ingredient in the labels of your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products, the product labeling clearly represents CBD as an active ingredient, which is a component of a drug intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body (see 21 CFR

201.66(b)(2)). For instance, your product labels and website repeatedly highlight the use of CBD for various conditions (see above claims), include numerous references to CBD with images of cannabis plants; and prominently feature CBD on the principal display panels of all of your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products. CBD is not a permitted active ingredient under the 1983 TFM.

Even if CBD could be considered an inactive ingredient in your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products, these products would still need an approved drug application to be legally marketed because they would not meet the requirements for marketing under section 505G of the FD&C Act. In particular, these products would not meet the conditions under section 505G(a)(1), insofar as they would not conform with the general requirement in 21 CFR 330.1(e) that inactive ingredients must be safe and suitable.[1] A suitable inactive ingredient generally provides a beneficial formulation function, such as a tablet binder or preservative, or improves product delivery (e.g., enhances absorption or controls release of the drug substance).[2] CBD has no known functional role as an inactive ingredient in a finished drug product. Additionally, an inactive ingredient should not exert pharmacological effects[3] and must be safe when used at the intended dosage.[4] CBD, however, has known pharmacological activity with demonstrated risks.[5] It is unknown whether the levels of CBD used in your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products have pharmacological activity or pose any concern for safety events. Accordingly, CBD cannot be considered a safe and suitable inactive ingredient as required under 21 CFR 330.1(e). Consequently, if CBD is intended to be an inactive ingredient in your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" product, that product would not meet the general requirements for nonprescription drugs needed for legal marketing under sections 505G(a)(1). Thus, "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" do not meet requirements under section 505G of the FD&C Act, under which they would be deemed to be GRASE and not a new drug.

In addition, FDA is not aware of any adequate and well-controlled clinical studies in the published literature that support a determination that "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling. Moreover, there is no evident basis under the FD&C Act under which these products would be legally marketed without an approved application. Accordingly, "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" are unapproved new drugs marketed in violation of section 505(a) of the FD&C Act, 21 U.S.C 355(a). Introduction or delivery for introduction of such products into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d).

Misbranded Human Drugs

Your "300 mg CBD Full Spectrum Oil Cannabinoid Tincture", "600 mg CBD Full Spectrum Oil Cannabinoid Tincture," "1500 mg CBD Full Spectrum Oil Cannabinoid Tincture," "500 mg Pain Relief Cream," "1000 mg Pain Relief Cream," "1000 mg CBD Anti-Aging Beauty Cream," "CBD Super Cider," and "CBD Super Food" 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).

Furthermore, your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products are also misbranded under section 502(a) of the FD&C Act because the labeling of these products is false and misleading for several reasons. First, the labeling for these products identifies CBD as an inactive ingredient but represents CBD as having purported active pharmacological properties such as pain relief, among others. Even if CBD could be considered an inactive ingredient in these products, the prominent featuring of CBD on the labeling of your "500 mg Pain Relief Cream" and "1000 mg Pain Relief Cream" products causes the products to be misbranded under section 502(a) of the FD&C Act, which deems a drug to be misbranded if its labeling is "false or misleading in any particular," and under 21 CFR 201.10(c)(4). Under 21 CFR 201.10(c)(4), "[t]he labeling of a drug may be misleading by reason . . . [of] the featuring in the labeling of inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation."

301(ll) and Adulterated Foods

We note that some of your products appear to be promoted or labeled as conventional foods. For example, your "CBD Super Cider" product is promoted as having a "delicious taste" and that it will not "have that sickeningly, sweet taste that most drinks offer." Additionally, your "CBD Super Cider" and "CBD SuperFood" products are labeled with a Nutrition Facts label. Your "300 mg CBD Full Spectrum Oil Cannabinoid Tincture", "600 mg CBD Full Spectrum Oil Cannabinoid Tincture" and "1500 mg CBD Full Spectrum Oil Cannabinoid Tincture" products, which are taken sublingually, also bear a Nutrition Facts label. 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, including 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.[6] 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

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.

According to your product labeling, your "CBD Super Cider" and "CBD SuperFood" products are foods to which CBD has been added. Therefore, the introduction or delivery for introduction into interstate commerce of those products is a prohibited act under section 301(ll) of the FD&C Act.

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.[7]

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

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) 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, www.renasorganic.com, and your social media websites, www.facebook.com/RenasOrganic and www.instagram.com/renasorganic, FDA determined that your firm is marketing the unapproved new animal drug "Rena's Organic For Pets 300mg CBD." Based on our review of your website and social media websites, your "Rena's Organic For Pets 300mg CBD" is a drug under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because it is 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, this product is an unapproved new animal drug and marketing it violates the FD&C Act.

Examples of claims observed on your website www.renasorganic.com, and your social media websites, www.facebook.com/RenasOrganic and www.instagram.com/renasorganic, that establish the intended use of your "Rena's Organic For Pets 300mg CBD" as a drug include, but are not limited to, the following:

On your product webpage for "Rena's Organic For Pets 300mg CBD" at https://renasorganic.com/products/renas-organic-for-pets/:

• "Whatever ailment your pet is suffering from, CBD or Cannabidiol, has shown extremely promising results."

On your blog post titled "4 Uses for CBD for Your Pets" at https://renasorganic.com/4-uses-for-cbd-for-your-pets/:

• "Small scale studies have shown that CBD can help calm anxious pets without compromising their health, so they're easier to manage."

• "Let's look at some of the uses of CBD for your pets:

1. CBD as a Painkiller
CBD is known for its anti-inflammatory properties that make it an effective painkiller for humans and animals. If your pet was injured in an accident, try massaging the effective area with potent CBD oils to reduce the
inflammation and pain. . . .

2. CBD is an Anticonvulsant
It's not very common, but pets can have seizures too. Seeing your pet have a seizure is the traumatizing, to say the least. If your pet has a condition that causes seizures or tremors, use CBD to reduce them. CBD is an anticonvulsant; it's proven to be very effective at

treating epilepsy and other similar conditions.

3. CBD for Anxiety and Stress
Owners struggling to manage an anxious pet can use CBD to calm them down. Both dogs and pets can suffer from anxiety in the same way humans do. If you notice that your pet hides in one corner of the house or gets aggressive when you're trying to leave the house, you can use CBD to put them at ease. CBD relaxes animals by reducing stress and anxiety.

4. CBD as an Antiemetic
Is your pet vomiting everywhere due to certain illnesses? Try giving them some CBD brands ; it's a known antiemetic and can help control nausea and vomiting. Your "Rena's Organic for Pets" website metadata includes the following tag:
• "product_tag-dog-cancer-cbd"

On your webpage titled, "What is CBD?" at https://renasorganic.com/what-is-cbd/:

• "Many pet owners are faced with watching their pets suffer from many of the same diseases that humans are inflicted with. There are more and more reports of animals being treated for these and other ailments successfully with CBD."

On your January 12, 2021 Facebook post www.facebook.com/RenasOrganic:

• "If something is making your pet anxious or tense, use our organic CBD Pet Product to help soothe them:"

On your January 6, 2021 Instagram post at www.instagram.com/renasorganic:

• "Try using our CBD product for pets. It can help reduce anxiety and calm down your furry companions. #CBD #CBDProducts #CBDforPainRelief #CBDforAnxiety #CBDforArthritis #CBDforStress #StressRelief #Anxiety"

Your "Rena's Organic For Pets 300mg CBD" product is a "new animal drug" under section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because it is 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-1. This product is not approved or index listed by the FDA, and therefore this product is 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 this adulterated drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations

that exist in connection with your products. You are responsible for investigating and determining the causes of any violations 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 address the violations cited in this letter. Failure to promptly address these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

This letter notifies you of our findings and provides you an opportunity to address the above violations. Please notify this office in writing within fifteen working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of any 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 completely address any violations within fifteen working days, state the reasons for the delay and your schedule for completion.

Your written response should be directed to the Food and Drug Administration, attention to: Mr. Ramon Hernández, District Director, 466 Fernández Juncos Avenue, San Juan, Puerto Rico 00901-3223. If you have any questions regarding this letter, please contact, Ms. Marilyn Santiago, Compliance Officer, at (787) 729-8707 or via email at Marilyn.santiago@fda.hhs.gov.

Sincerely,
/S/

Ramon A. Hernandez
District Director | FDA San Juan District
Program Division Director
Office of Human and Animal Food Operations-
East Division

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1 21 CFR 330.1(e) requires that "the product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity".

2 See, e.g., "*Using the Inactive Ingredient Database*" Guidance for Industry (July 2019), p. 1 at https://www.fda.gov/media/128687/download, and "*Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients*" Guidance for Industry (May 2005), pp. 1-2 at https://www.fda.gov/media/72260/download.

3 See, e.g., 21 CFR 314.3(b) and 21 CFR 210.3(b)(7), which define an active ingredient as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the

structure or any function of the body of man". All other components of a finished drug product are considered inactive ingredients (see CFR 314.3(b), 21 CFR 210.3(b)(8)).

4 See 21 CFR 330.1(e).

5 For example, the labeling for Epidiolex (cannabidiol) prescription oral solution includes risks for the drug such as liver injury, interactions with other drugs or supplements, potential for male reproductive toxicity, somnolence, insomnia, diarrhea, decreased appetite, abdominal pain, upset stomach, changes in mood, irritability, and agitation. See https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf.

6 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 ***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.

7 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 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.

WARNING LETTER

BioMD Plus LLC

MARCS-CMS 618460 — MAY 04, 2022

More Warning Letters

Warning Letters

About Warning and Close-Out Letters

Delivery Method: Via Email

Product: Animal & Veterinary
Drugs
Food & Beverages

Recipient:
Jonathan M. Levitt
BioMD Plus LLC
1371 Sheffield Pkwy
Marietta, GA 30062
United States

support@biomdplus.com

Issuing Office:
Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

May 4, 2022

RE: #618460

Dear Jonathan Levitt:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at www.biomdplus.com in February 2022 and has determined that you take orders there for various human and animal products, which you represent as containing cannabidiol (CBD) or Delta-8 tetrahydrocannabinol (THC)

Content current as of:
05/04/2022

Regulated Product(s)
Animal & Veterinary
Drugs
Food & Beverages

We have also reviewed your social media websites at https://twitter.com/bioMDplus, https://www.facebook.com/bioMDplus/ and https://www.instagram.com/biomdplus/, which direct consumers to your website www.biomdplus.com to purchase your products. The claims on your website and social media accounts establish that your products, some of which are available in multiple varieties, "CBD Oil," "CBD Capsules," "Vegan CBD Gummies," "CBD Pain Relief Cream," "Delta 8 THC Gummies," and "Delta 8 THC Vape Cartridge" (hereinafter referred to as "your CBD and Delta-8 THC products for humans") are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1).

In addition, your "Natural Pet CBD Oil" is an unapproved new animal drug that is unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and is adulterated under section 501(a)(5) of the FD&C Act, 21 U.S.C. 351(a)(5).

FDA has also determined that certain food products that you market are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive.

As explained further below, introducing or delivering these products for introduction into interstate commerce violates the FD&C Act. You can find specific information about how FDA regulates cannabis-derived products at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

Over the past several years, FDA has warned the public on various illegally marketed CBD-containing products. FDA has also observed a proliferation of products containing another cannabinoid, Delta-8 THC, and has recently expressed serious concerns about products containing Delta-8 THC that include: 1) Delta-8 THC products have not been evaluated or approved by FDA for safe use and may be marketed in ways that put the public health at risk; 2) FDA has received adverse event reports involving Delta-8 THC containing products; 3) Delta-8 THC has psychoactive and intoxicating effects; 4) FDA is concerned about the processes used to create the concentrations of Delta-8 THC claimed in the marketplace; and 5) FDA is concerned about Delta-8 THC products that may be consumed by children, as some packaging and labeling may appeal to children. See https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc. This letter is to inform you that your firm markets Delta-8 THC-containing products, and Delta-8 THC may pose a serious health risk to consumers.

Dietary Supplement Labeling

Information on your website at www.biomdplus.com indicates that you appear to market your CBD-containing "CBD Capsules" and "Vegan CBD Gummies" as dietary supplements. For example, the product webpages display a product label image with "hemp supplement" on them. However, your products cannot be dietary supplements because they do 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

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 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.

Unapproved New Human Drugs

Based on a review of your website and social media accounts, your CBD and Delta-8 THC products for humans 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 from your website www.biomdplus.com and social media accounts, https://twitter.com/bioMDplus, https://www.facebook.com/bioMDplus/ and https://www.instagram.com/biomdplus/, that provide evidence of the intended use of these products as drugs include, but may not be limited to, the following:

From your website www.biomdplus.com:

On your blog post titled, "Best CBD Oil for Stress & Depression: Can CBD Oil Help?":

- "Many are turning to consume CBD oil for anxiety, depression, and bipolar disorder."
- "The pre-clinical data support the possible use of CBD with Panic Disorder (PD), Obsessive-Compulsive Disorder (OCD), and Post Traumatic Stress Disorder (PTSD), and Bipolar Disorder."

On your blog post titled, "CBD for Psychosis vs CBD Oil for Schizophrenia: Breaking News…":

- "People are now taking CBD for anxiety, stress relief, proper pain medication, and to help fight addiction."
- "High-level CBD can help manage symptoms of psychosis that come from schizophrenia."

On your blog post titled, "CBD Oil Benefits":

- "Relief for Chronic Pain . . . . [t]hose who suffer from chronic pain from diseases such as fibromyalgia find relief in CBD. Taking CBD can relieve pain and even prevent the degeneration of the nervous system."
- "IBD . . . . [s]everal studies have suggested that one of the most important effects of CBD is that it may help patients with inflammatory bowel disease such as ulcerative colitis and Crohn's disease."

On your blog post titled, "CBD Oil for Sundowning, Dementia, Alzheimer's Disease & Disorientation":

- "The dementia-related conditions that can be helped by CBD Oil include Alzheimer's disease, Vascular Dementia, Dementia with Lewy bodies (DLB), Parkinson's disease, Frontotemporal dementia and Huntington's disease."
- "CBD could help remove dementia from brain cells."

On your blog post titled, "Delta-8 THC: Discover This New Cannabinoid from Cannabis":

- "[D]elta-8-THC was administered to eight children being treated for hematologic cancers. The children were 3 to 13 years old . . . [t]hey all experienced vomiting because of the chemo . . . . they received delta-8-THC with their chemotherapy treatments, every single child stopped vomiting during and after their chemo sessions!"
- "[D]elta-8-THC has also been used to relieve pain, ease anxiety"

On your blog post titled, "How Long Does It Take For Results Using CBD Oil To Take Affect With OCD?":

- "CBD oil is an effective natural treatment for OCD."

On your blog post titled, "How To Take CBD Oil For Crohn's Disease? Finding The Right Dosage":

- "The study suggests that cbd oil or a derivative of it could be a useful treatment for Crohn's."

On your blog post titled, "Is CBD Oil Good For Idiopathic Pulmonary Fibrosis? The Ultimate Therapeutic Guide":

- "[T]here are numerous studies that suggest CBD oil has the potential to treat a wide variety of health issues and could be effective in treating IPF [idiopathic pulmonary fibrosis]."

On your Delta 8 Gummies product webpage:

- "Another benefit that many people don't know is that Cannabidiol can help with the growth and healing of damaged tissue, and it can also help reduce chronic pain and the likelihood of developing certain cancers, such as breast and prostate."
- "The benefits of Delta 8 are the following . . . Reduce depression . . . Reduce anxiety and panic attacks . . ."

On your CBD Pain Relief Cream webpage:

- "bioMDplus Pain Cream in 500mg strength is a new formulated pain relief topical cream that made for use on sore muscle areas and areas where there is pain. bioMDplus Pain Cream infused with the Quality Full Spectrum CBD. bioMDplus CBD Cream provides effective, fast and long-lasting pain relief."
- "Begin by rubbing small amounts of CBD cream to the affected area and wait for about an hour. You can increase the quantity depending on how fast it works. If the effects of the cream are slow to kick in, then its [*sic*] recommended to re-apply CBD cream after every 3-4 hours. . . . Using CBD cream is like using a moisturizing lotion, but making sure to apply the optimal dosage of CBD cream isn't easy. Users have to determine the milligrams of CBD in the cream and decide whether it's good enough for pain relief. CBD creams with low amounts of CBD will probably be less useful than those with higher concentrations. Begin by using small amounts of CBD cream before slowly increasing it until you find relief. Moreover, applying CBD cream on the body isn't known to produce any significant side effects."
- "CBD creams work when directly applied to the skin, which makes them an excellent alternative to traditional creams when it comes to pain relief. . . . For the most part, the effects of CBD cream can be felt 15-20 minutes and can keep working for as long as 6 hours or more."
- "Applying CBD-infused creams is generally a straightforward process. Look for the areas of your body

most affected by pain and discomfort, and apply small amounts of CBD cream around those areas for local treatment. . . . Elbows, knees, and joint . . . Bottoms of the feet and impact points . . . Face, particularly around the temples and the nose . . . Neck and shoulders"

From your social media websites:

On your Facebook Social Media page https://www.facebook.com/bioMDplus/:

- July 28, 2020 post – "Recent research has linked CBD with several benefits for the heart and circulatory system, including the ability to lower high blood pressure. High blood pressure is linked to higher risks of a number of health conditions, including stroke, heart attack, and metabolic syndrome."
- April 14, 2020 post – "500mg: CBD & Menthol Pain Cream . . . bioMDplus 500mg CBD Pain Cream is a newly formulated pain relief topical cream made to soothe sore muscles and alleviate chronic joint pain. Derived from our signature potent hemp oil infused with peppermint oil, eucalyptus oil, menthol and our signature terpene blend, this cream allows for a unique and STRONG combination of natural ingredients and CBD to aid in POWERFUL relief. You can use our new topical pain cream to FIGHT back against sore muscles and achy joints!"
- April 7, 2020 post – "Just what does CBD do for the body and why are people so interested in this substance? . . . Pain relief from arthritis or inflammatory diseases . . . Treatment of insomnia . . . Lowering anxiety levels . . . May lower diabetes risk . . . Could lower levels of obesity"

On your Twitter Social Media Page https://twitter.com/bioMDplus:

- August 4, 2021 post – "62% of CBD users used it to treat health conditions. The most common uses were for pain, anxiety and depression."
- July 25, 2021 post – "CBD Oil for Depression, Anxiety, and Bipolar disorder."

On your Instagram Social Media Page https://www.instagram.com/biomdplus/:

- July 4, 2020 post – "75% of PTSD patients saw a reduction in PTSD symptoms, when they were using CBD products compared to when they were not."
- November 5, 2019 post – "A recent study showed that CBD administration can prevent the death of the neurons and reduce brain damage in the event of a stroke. CBD also reduced stroke-related seizures."

Based on the above labeling claims, your CBD and Delta-8 THC products for human use are drugs. We are not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that any of these products are generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended or suggested in their labeling. Thus, your CBD and Delta-8 THC products for human use are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here,[2] new drugs may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a), 331(d). No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for your CBD and Delta-8 THC products for humans. There is no basis under the FD&C Act under which these products would be legally marketed without an approved application. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

Misbranded Human Drugs

Your CBD and Delta-8 THC products for humans 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.) These 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. Under 21 CFR 201.100(c)(2) and 201.115, 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, because no FDA-approved applications are in effect your products.[3]

The introduction or delivery for introduction into interstate commerce of misbranded drugs is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

CBD-containing Drugs

Even if your "CBD Pain Relief Cream" was considered a nonprescription drug, we note that a nonprescription drug product containing CBD cannot be legally marketed without an approved new drug application, regardless of whether the CBD is represented on the labeling as an active ingredient or an inactive ingredient. To date, no CBD-containing drug has met applicable FDA requirements to be legally marketed for nonprescription use. Nonprescription drug products that include CBD as an active ingredient are not GRASE and are new drugs which require an approved application to be legally marketed. CBD is not an active ingredient in any OTC monograph under section 505G of the FD&C Act. Even if CBD could be considered an inactive ingredient in a nonprescription drug product, that product would still need an approved new drug application to be legally marketed, because the product would not meet the general requirements under section 505G of the FD&C Act under which certain nonprescription drug products may be marketed without an approved new drug application. In particular, such a product would not meet the general requirement with respect to the safety and suitability of inactive ingredients under 21 CFR 330.1(e).[4], [5]

Adulterated Human Foods

According to your product labeling, your "Delta 8 THC Gummies" product is a food to which Delta-8 THC has been added.

You should 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 it 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.[6]

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 that authorizes the use of Delta-8 THC. We are not aware of any

information to indicate that Delta-8 THC is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that Delta-8 THC 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 Delta-8 THC 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 Delta-8 THC in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from Delta-8 THC. Our review of published scientific literature identified potential for adverse effects on the central nervous and cardiopulmonary systems. In addition, studies in animals have suggested that gestational exposure to Delta-8 THC can interfere with neurodevelopment. Therefore, based on our review, the use of Delta-8 THC in your 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 Delta-8 THC for use as an ingredient in a conventional food. Therefore, Delta-8 THC 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. Delta-8 THC 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) of the FD&C Act. Therefore, your "Delta 8 THC Gummies" are adulterated within the meaning of section 402(a)(2)(C)(i) of the FD&C Act because they bear or contain an unsafe food additive. Introduction of these 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

Based on our review of your website and social media websites, your "Natural Pet CBD Oil" is a drug under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because it is 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, this product is an unapproved new animal drug and marketing it violates the FD&C Act.

Examples of claims from your website https://biomdplus.com, and your social media websites https://www.facebook.com/bioMDplus/, https://www.instagram.com/biomdplus/, and https://twitter.com/biomdplus, that provide evidence of the intended use of your "Natural Pet CBD Oil" as a drug include, but are not limited to, the following:

On your product page for "Natural Pet CBD Oil":

- "Whether you're using CBD oil for pain relief or anxiety, the right full spectrum CBD oil for dogs dosage depends on a number of factors. . . ."
- "[L]inalool [an ingredient in your Natural Pet CBD Oil] may relieve . . . depression."
- "Humulene [an ingredient in your Natural Pet CBD Oil] . . . may help to reduce inflammation."

On your webpage blog titled, "How Effective Is CBD For Pets?":

- "CBD tinctures are reported to help pets with seizures."

Top

- "CBD tinctures are reported to help pets with seizures."
- "Thanks to the natural anti-inflammatory properties in CBD, it also makes for a great candidate in helping with anxiety, inflammation, and arthritis."
- Under the heading "Top Uses CBD for Pets":
    - "Anxiety[:] One of the major benefits reported with CBD is that it can help . . . alleviate their anxiety. Most pets will suffer from varying degrees of anxiety, especially dogs and cats."
    - "Pain . . . CBD can greatly help with [pain]. So any inflammatory pain that your pet may be suffering from may be greatly reduced with CBD. Since CBD has natural anti-inflammatory properties, it works especially well for inflammation-induced pain."
    - "Arthritis[:] Although there are yet to be more tests on the effectiveness of CBD against arthritis, there is a substantial reason and some tests that prove its efficacy. Of course, the inherent anti-inflammatory properties of CBD do make it very valuable in providing substantial relief to arthritis. Moreover, research also supports these claims, ensuring that CBD can be a good substitute for regular arthritis medicine."
    - "Seizures[:] Seizures among pets can be a very serious concern, but research suggests that CBD can help in reducing certain types of seizures in dogs. . . . In dogs, research conducted on idiopathic epilepsy showed that CBD assisted in reducing the intensity of seizures. So if your dog suffers from the condition, CBD can prove to be useful in bringing relief."

On your webpage blog titled, "Full Spectrum CBD Oil for Dogs":

- "Here are a few problems full-spectrum CBD oil can help treat:"
    - "Pain Including Joint Pain[:] It's believed that CBD oil can reduce pain, especially neuropathic pain in dogs. It's also said to be effective in reducing joint pain and arthritis, which is why it's often recommended for older dogs."
    - "Inflammation[:] CBD oil is anti-inflammatory and can help reduce chronic inflammation in dogs due to genetics, parasites, metabolic diseases, food allergies, bacterial overgrowth, and environmental stress."
    - "Anxiety[:] If your dog gets stressed or anxious then you may consider using CBD oil as it has been linked to less anxiety and stress."
    - "Digestion Problems . . . Regular use of full-spectrum CBD oil for dogs can treat this problem as it's said to eliminate digestive issues"
    - "Pain Symptoms[:] There are reasons to believe that the best full-spectrum CBD oil for dogs can help alleviate symptoms of pains in dogs. . . . The use of CBD oil may not cure the disease but it can help reduce the pain and suffering."
    - "Seizures[:] Some experts are of the belief that regular use of full-spectrum CBD oil can reduce the risk of seizures in dogs. The AKC Canine Health Foundation is working with the Colorado State University to evaluate the use of full-spectrum CBD oil in treatment-resistant epileptic dogs. biomdplus offers the best full-spectrum CBD oil for dogs. Our product is meant to provide all the above-mentioned benefits to dogs of all ages."

On both your Facebook and Instagram social media websites at https://www.facebook.com/bioMDplus/ and https://www.instagram.com/biomdplus/ respectively:

and https://www.instagram.com/bioMDplus respectively.

- Facebook and Instagram July 23, 2020 postings with a photograph of a cat looking at your "Natural Pet CBD Oil" product:
    - "Use bioMD+ CBD products made for cats to help with . . . pain"
- Facebook and Instagram October 5, 2019 postings with a photograph of a dog licking a woman's face:
    - "For pets who . . . have swollen joints, or separation anxiety CBD has helped many!"

On your Twitter social media website at https://twitter.com/bioMDplus:

- October 13, 2020 posting of a graphic titled "CBD FOR PETS . . . What can CBD do for your pet?" (checklist at the bottom next to clipboard titled "CONDITIONS TREATED"):
    - "? Allergies"
    - "? Anxiety"
    - "? Cancer Management"
    - "? Inflamation *[sic]*"
    - "? Glaucoma"
    - "? Skin Irritation"
    - "? Seizures and Epilepsy"
    - "? Arthritis"

Your "Natural Pet CBD Oil" product is a "new animal drug" under section 201(v) of the FD&C Act, 21 U.S.C. 321(v), because it is 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-1. This product is not approved or index listed by the FDA, and therefore this product is 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 this adulterated drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

* * *

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations 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.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action 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 by email to FDAADVISORY@fda.hhs.gov.

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

/S/
Neal Bataller
Director
Division of Drug Compliance
Office of Surveillance & Compliance
Center for Veterinary Medicine
Food and Drug Administration

/S/
Ann Oxenham
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

[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 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] For example, under section 505G of the FD&C Act, 21 U.S.C. 355h, certain nonprescription drug products may be lawfully marketed without an approved application if applicable conditions are met, including conformity with an applicable OTC monograph. However, your products could not be lawfully marketed under section 505G, because based on your claims regarding these products, including

on your website labeling, your products are marketed for uses not considered nonprescription indications. Further, even if certain of your products, such as your "CBD Pain Relief Cream" were marketed only for nonprescription indications, they would not meet the conditions under section 505G for lawful marketing without an approved application. For example, CBD — considered an active ingredient under 21 CFR 201.66(b)(2) due to its prominent featuring on your product labeling — is not an active ingredient in any OTC monograph under section 505G of the FD&C Act.

[3] Further, even if your products were marketed only for nonprescription indications, these products would be misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they would be nonprescription drugs subject to section 505G of the FD&C Act that do not comply with the requirements for marketing under that section (see footnote 1) and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355.

[4] 21 CFR 330.1(e) requires in relevant part that "the product contains only suitable inactive ingredients which are safe in the amounts administered." A suitable inactive ingredient generally provides a beneficial formulation function, such as a tablet binder or preservative, or improves product delivery (e.g., enhances absorption or controls release of the drug substance). CBD has no known functional role as an inactive ingredient in a finished drug product.

[5] Additionally, an inactive ingredient should not exert pharmacological effects and must be safe when used at the intended dosage. CBD has known pharmacological activity with demonstrated risks. For example, the labeling for Epidiolex (cannabidiol) prescription oral solution includes risks for the drug such as liver injury, interactions with other drugs or supplements, potential for male reproductive toxicity, somnolence, insomnia, diarrhea, decreased appetite, abdominal pain, upset stomach, changes in mood, irritability, and agitation. See https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf. It is unknown whether the levels of CBD used in your CBD products have pharmacological activity or pose any concern for safety events.

[6] 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.

WARNING LETTER

Kingdom Harvest

MARCS-CMS 625058 — MAY 04, 2022

More Warning Letters

Warning Letters

About Warning and Close-Out Letters

Delivery Method: Via Email

Product: Animal & Veterinary
Drugs
Food & Beverages

Recipient:
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Issuing Office:
Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

May 4, 2022

RE: # 625058

Dear Ms. Rogers:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address www.kingdomharvest.com from October 2021 through April 2022 and has determined that you

Content current as of:
05/04/2022

Regulated Product(s)
Animal & Veterinary
Drugs
Food & Beverages

internet address www.kingdomharvest.com from October 2021 through April 2022 and has determined that you take orders there for various human and animal products, which you represent as containing cannabidiol (CBD) or Delta-8 tetrahydrocannabinol (THC). We have also reviewed your social media websites at https://www.facebook.com/originalkingdomharvest/ and https://www.instagram.com/kingdomharvest/?hl=en; which direct consumers to your website www.kingdomharvest.com to purchase your products. The claims on your website and social media accounts establish that your products, some of which are available in multiple varieties, "D8 sublingual oil," "Delta 8 Disposable Vape Cartridge," "Whole-Spectrum Hemp Extract," "CBD Vape," "Blood Sugar Support," "CBD Gummies," "Stella's Baby Care Diaper Cream," "Pain Relieving CBD Cream," "Pain Relieving Cream," "CBD & Menthol Pain Freeze Roll-On," "Immune Boost Water Soluble Mix," "Broad-Spectrum THC Free Organic Honey," "CBD Fair-Trade Coffee," "CBD Infused Organic Tea," "Delta 8 Chewing Gum," "Delta 8 Gummies," "Delta 8 Peanut Brittle," and "Delta 8 Syrup," (hereinafter referred to as "your CBD and Delta-8 THC products for humans"), 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 CBD and Delta-8 THC products for humans are misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1).

FDA has also determined that your "Broad-Spectrum THC Free Organic Honey," "CBD Fair-Trade Coffee," "CBD Infused Organic Tea," "Delta 8 Chewing Gum," "Delta 8 Gummies" (all varieties), "Delta 8 Peanut Brittle," "Delta 8 Syrup," "Ranch & Livestock Natural Whole-Spectrum Hemp Extract," "Canine Whole-Spectrum Hemp Extract," "Feline Chicken Flavor Zero THC Hemp Extract," and "Pet Essentials Joint Support Tablets" products are adulterated under section 402(a)(2)(C)(i) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(i), because they bear or contain an unsafe food additive. Furthermore, it is a prohibited act to introduce your "Broad-Spectrum THC Free Organic Honey," "CBD Fair-Trade Coffee," "CBD Infused Organic Tea," "Ranch & Livestock Natural Whole-Spectrum Hemp Extract," "Canine Whole-Spectrum Hemp Extract," "Feline Chicken Flavor Zero THC Hemp Extract," and "Pet Essentials Joint Support Tablets" products into interstate commerce under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll).

In addition, the claims on your website and social media websites establish that your products, "Ranch & Livestock Natural Whole-Spectrum Hemp Extract," "Canine Whole-Spectrum Hemp Extract," "Feline Chicken Flavor Zero THC Hemp Extract," "Pet Essentials Joint Support Tablets," "CBD Infused Pet Shampoo," and "CBD Infused Pet Paw Balm," which you promote as products containing CBD for use in animals, are unapproved new animal drugs that are unsafe under section 512(a) of the FD&C Act, 21 U.S.C. 360b(a), and are 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 specific information about how FDA regulates cannabis-derived products at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

The Agency is particularly concerned that you market CBD products for food-producing animals. Specifically, your website promotes your "Ranch & Livestock Natural Whole-Spectrum Hemp Extract" product for use in cows and other large variety ranch and livestock animals. In addition to raising potential concerns regarding safety for the animals themselves, CBD products for food-producing animals raise concerns regarding the safety of the human food (meat, milk, and eggs) derived from those animals. There is currently a lack of data on the formation of residues in edible products of food-producing animals in association with the consumption of CBD products by those animals and on safe levels of any potential residues for the human consumer. We request that you take immediate action to cease the sale of any unapproved CBD products for food-producing

animals.

Over the past several years, FDA has warned the public on various illegally marketed CBD containing products, including those marketed for infants, such as your "Stella's Baby Care Diaper Cream."[1] FDA has also observed a proliferation of products containing another cannabinoid, Delta-8 THC, and has recently expressed serious concerns about products containing Delta-8 THC that include: 1) Delta-8 THC products have not been evaluated or approved by FDA for safe use and may be marketed in ways that put the public health at risk; 2) FDA has received adverse event reports involving Delta-8 THC containing products; 3) Delta-8 THC has psychoactive and intoxicating effects; 4) FDA is concerned about the processes used to create the concentrations of Delta-8 THC claimed in the marketplace; and 5) FDA is concerned about Delta-8 THC products that may be consumed by children, as some packaging and labeling may appeal to children. See https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc. This letter is to inform you that your firm markets Delta-8 THC-containing products, and Delta-8 THC may pose a serious health risk to consumers.

We also observed that your website makes claims that your products may be intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.[2]

Dietary Supplement Labeling

Information on your website at www.kingdomharvest.com indicates that you intend to market some of your CBD products, including, but not limited to, "Immune Boost Water Soluble Mix," and all varieties of "Blood Sugar Support" and "CBD Gummies" as dietary supplements. For example, the product website describes "Immune Boost Water Soluble Mix" with reference to the goal of creating a "high-quality supplement" and the product websites expressly describe each "Blood Sugar Support" and "CBD Gummies" product as a "dietary supplement." Your products cannot be dietary supplements because they do 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.[3] There is an exception if the substance was "marketed as" a dietary supplement or as a conventional human 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 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.

Unapproved New Human Drugs

Based on a review of your websites, your CBD and Delta-8 THC products for humans 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

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 product labeling, including your website and social media websites, that provide evidence of the intended use of these products as drugs include, but may not be limited to, the following:

From your Facebook and Instagram social media websites www.facebook.com/originalkingdomharvest/ and www.instagram.com/kingdomharvest/:

- May 11, 2020 postings:
  - "Cannabidiol (CBD) changes neurotransmission systems . . . Alters behavior response to Opioids . . . Pain management during Opioid withdrawal . . . Reduces Heroin cravings and relapse"
  - "Fighting Opioid Addiction with Whole-Spectrum Hemp Extract . . . CBD Oil (otherwise known as cannabidiol) is scientifically proven to block the rewards of opioids"
  - "CBD Reduces Need for Opioid Use in Pain Treatment"
  - "64-81% of acute trauma patients reduced opioid usage with cannabis while still managing pain"
- April 27, 2020 postings:
  - "Israeli researchers have launched three clinical trials that utilize CBD's anti-inflammatory properties as potential COVID-19 treatment . . . Last week, InnoCan Pharma announced a collaboration with Tel Aviv University to instill CBD medicine through exosomes . . . The unconventional method will utilize the exosomes as "homing missiles," as they can uniquely target cell organs damaged by COVID-19. Researchers then believe CBD's anti-inflammatory properties will repair the damaged cells through a synergistic effect."
  - "The Battle Against COVID-19 Has A New Natural Weapon . . . University Launches CBD Treatment . . . kingdomharvest.com"
- April 7, 2020 postings – "Whole-Spectrum Hemp Extract & CBD & The Fight Against COVID-19."

From your website https://kingdomharvest.com/:

On your website homepage:

- "Studies Show Our Whole-Spectrum Extract Utilizing CBDa Can Prevent Infection From COVID-19"

On your blog post titled, "Cannabinoids Block Cellular Entry of COVID-19 and the Emerging Variants":

- "Importantly, cannabigerolic acid and cannabidiolic acid were equally effective against the SARS-CoV-2 alpha variant B.1.1.7 and the beta variant B.1.351."
- ". . . [C]annabinoids . . . have the potential to prevent as well as treat infection by SARS-CoV-2."

On your blog post titled, "Let's [*sic*] Us Introduce You to Delta-8 THC":

- "If we try to list the properties or the effects of Delta-8 THC, it causes . . . pain relief, full-body relaxation and sleep."
- "Delta-8 THC flower is an ideal option for medical users of cannabis who want to enjoy the benefits of

THC without the sedative effects."

On your blog post titled, "How Does CBD Work for Relieving Pain & The Best CBD Pain Relief Product?":

- "CBD is among the most misinterpreted things on the planet . . . It is a magical medicine that has provided relief for countless people with chronic pain, from cancer pain to arthritis pain, migraine pain, body pain, and much more."

On your blog post titled, "Discover the Benefits of CBD for Your Health and Wellness":

- "Hemp CBD can improve your overall health and wellbeing by providing relief for several medical ailments, including chronic pain, depression, anxiety, epilepsy"
- "Other benefits of hemp CBD include managing post-traumatic stress disorder (PTSD), sleep disorders and cancer treatments."
- "CBD has been shown to have positive effects on adults and children who experience PTSD."
- "One study found hemp CBD helps slow tumor growth, reduces tumor invasion and induces tumor cell death. Another study suggested CBD could provoke cell death and improve the effect of radiation on glioblastoma cells while causing no damage to healthy cells."
- "Initial studies have suggested CBD can help make life easier for an individual with Parkinson's by easing muscle movements to prevent tremors. There is also research that suggests CBD can reduce the severity of psychosis symptoms, including hallucinations, delirium and delusions without causing any adverse effects."

On your product webpage for "D8" sublingual oil:

- "Delta-8 consumers report many of the same effects as THC . . . and relief from some symptoms such as pain . . . Delta-8 can also help with insomnia."

On your product webpage for "Stella's Baby Care Diaper Cream":

- "Our Organic Diaper Cream contains our natural organic Whole-Spectrum Hemp Extract and just 7 other natural ingredients. In contrast, the leading diaper rash cream is 57% petroleum!"

On your webpage explaining the "Effects of delta-8":

- "Delta-8 consumers report many of the same effects as THC, such as . . . relief from some symptoms such as pain . . .. Delta-8 can also help with insomnia."

On your product webpage for "Delta-8 THC Syrup":

- "Delta-8 THC Syrup from Kingdom Harvest is ideal for anybody experiencing a sleeping disorder or other ailments looking to be relieved."

On your product webpage for "Blood Sugar Support":

- "Kingdom Harvest Blood Sugar support pills contain three active ingredients that work at the same time and may help you to maintain a healthy blood glucose level and prevent further complications."
- "Cinnamon powder contains many antioxidants that may help to reduce oxidative stress due to high blood glucose, improve insulin sensitivity, lower blood sugar levels, and prevent complications."

- "Meanwhile, alpha-lipoic acid . . . may help with glucose uptake in muscles and enhance insulin sensitivity."
- "Finally, cannabidiol (CBD) . . . prevents neurodegeneration, and decreases retinal complications."

On your product webpage for "Pain Relieving CBD Cream":

- "600MG • CBD / CAPSAICIN MUSCLE PAIN CREAM . . . This topical muscle and joint relief cream act [*sic*] through its two active ingredients: capsaicin and cannabidiol (CBD) . . . Capsaicin is an active component of chili peppers known to help reduce pain intensity. Meanwhile, CBD interacts with endocannabinoid receptors in joints and muscles to promote a healthy inflammatory response and relieve occasional stiffness and soreness. Capsaicin is also known to be a neuroprotectant, as it may protect nerves from being damaged or degenerated."

On your product webpage for "Pain Relieving Cream":

- "200 MG CBD / LIDOCAINE PAIN CREAM . . . The CBD with Lidocaine Cream contains the same main ingredient as the Capsaicin cream – CBD, which helps promote support and relief. However, the differing active ingredient is lidocaine, a local anesthetic."

On your product webpage for "CBD & Menthol Pain Freeze Roll-On":

- "800MG CBD / MENTHOL PAIN FREEZE . . . Our Pain Freeze Roll-On is a rich combination of our Organic Hemp Extract, Aloe, and Menthol. Available in a mess-free, roll-on applicator, this topical cream provides a rapid cooling effect, perfect for joint and muscle support."

Based on the above labeling claims, your CBD and Delta-8 THC products for humans are drugs. We are not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that any of these products are generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended or suggested in their labeling. Thus, your CBD and Delta-8 THC products for humans are "new drugs" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here,[4] new drugs may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in section 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a), 331(d). No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for your CBD and Delta-8 THC products for humans. There is no basis under the FD&C Act under which these products would be legally marketed without an approved application. Accordingly, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C 355(a) and 331(d).

Misbranded Human Drugs

Your CBD and Delta-8 THC products for humans 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.)

These 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. Under 21 CFR 201.100(c)(2) and 201.115, 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, because no FDA-approved applications are in effect for your products.[5] The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

CBD-containing Drugs

Even if your "Pain Relieving CBD Cream," "Pain Relieving Cream," "CBD & Menthol Pain Freeze Roll-On," and "Stella's Baby Care Diaper Cream" products were considered nonprescription drugs, we note that a nonprescription drug product containing CBD cannot be legally marketed without an approved new drug application, regardless of whether the CBD is represented on the labeling as an active ingredient or an inactive ingredient. To date, no CBD-containing drug has met applicable FDA requirements to be legally marketed for nonprescription use. Nonprescription drug products that include CBD as an active ingredient are not GRASE and are new drugs which require an approved application to be legally marketed. CBD is not an active ingredient in any OTC monograph under section 505G of the FD&C Act. Even if CBD could be considered an inactive ingredient in a nonprescription drug product, that product would still need an approved new drug application to be legally marketed, because the product would not meet the general requirements under section 505G of the FD&C Act under which certain nonprescription drug products may be marketed without an approved new drug application. In particular, such a product would not meet the general requirement with respect to the safety and suitability of inactive ingredients under 21 CFR 330.1(e).[6], [7]

301(ll) and Adulterated Human Foods

We note that your "Broad-Spectrum THC Free Organic Honey," "CBD Fair-Trade Coffee," and "CBD Infused Organic Tea" products appear to be conventional foods. 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, as described above. 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 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 section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll), 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.[8]

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 that 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. Some of the available data raise serious concerns about potential harm from CBD. 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, 21 USC 321(s), and is subject to the provisions of section 409 of the FD&C Act, 21 USC 348. 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) of the FD&C Act, 21 USC 342(a)(2)(C)(i). Therefore, your "Broad-Spectrum THC Free Organic Honey," "Fair-Trade Coffee," and "CBD Infused Organic Tea" conventional food products contain an unsafe food additive within the meaning of section 409; therefore they are adulterated products within the meaning of section 402(a)(2)(C)(i) of the FD&C Act. Introduction of these adulterated foods into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Further, there is no food additive regulation that authorizes the use of Delta-8 THC. We are not aware of any information to indicate that Delta-8 THC is the subject of a prior sanction (see 21 CFR Part 181). Furthermore, we are not aware of any basis to conclude that Delta-8 THC is GRAS for use in conventional foods.

We know of no basis for general recognition of safety for Delta-8 THC 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 Delta-8 THC in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from Delta-8 THC. Our review of published scientific literature identified potential for adverse effects on the central nervous and cardiopulmonary systems. In addition, studies in animals have suggested that gestational exposure to Delta-8 THC can interfere with neurodevelopment. Therefore, based on our review, the use of Delta-8 THC in conventional food does not satisfy the criteria for GRAS status under 21 CFR 170.30.

In addition, according to your product labeling, your "Delta 8 Chewing Gum," "Delta 8 Peanut Brittle," and

"Delta 8 Syrup" products are foods to which Delta-8 THC has been added. Specifically, your website promotes your "Delta 8 Syrup" for mixture with "any drink" and recommends "something carbonated." Your "Delta 8 Chewing Gum" and "Delta 8 Peanut Brittle" are types of products typically considered to be conventional foods. Your "Delta 8 Gummies" (all varieties) also appear to be conventional foods to which Delta-8 THC has been added.

FDA is not aware of any other exception to the food additive definition that would apply to Delta-8 THC for use as an ingredient in a conventional food. Therefore, Delta-8 THC 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. Delta-8 THC 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) 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 and your social media websites, FDA determined that your firm is marketing the unapproved new animal drugs "Ranch & Livestock Natural Whole-Spectrum Hemp Extract," "Canine Whole-Spectrum Hemp Extract," "Feline Chicken Flavor Zero THC Hemp Extract," "Pet Essentials Joint Support Tablets," "CBD Infused Pet Shampoo," and "CBD Infused Pet Paw Balm." Based on our review of your website and social media websites, these 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 website and your social media websites that establish the intended use of your products as drugs include, but are not limited to, the following:

On your Frequently Asked Questions (FAQ) webpage at https://kingdomharvest.com/pages/faq, you provide the following information about CBD, which is an ingredient in "Ranch & Livestock Natural Whole-Spectrum Hemp Extract," "Canine Whole-Spectrum Hemp Extract," "Feline Chicken Flavor Zero THC Hemp Extract," "Pet Essentials Joint Support Tablets," "CBD Infused Pet Shampoo," and "CBD Infused Pet Paw Balm":

- "Many CBD users have reported improvements in:
    - Stress
    - Anxiety
    - Sleep
    - Pain levels
    - Skin conditions including acne and eczema
    - Epilepsy"

On your product webpage for "Ranch & Livestock Natural Whole-Spectrum Hemp Extract":

- "Like humans, our larger Ranch & Livestock pets have Endocannabinoid Systems that help bring balance to their bodies. Introducing a whole-spectrum hemp extract into your horses, cows, alpacas, and any other large variety Ranch & Livestock animals on a daily routine can help promote an overall balance and improved quality of life. Senior Ranch & Livestock Animals & Pets, those that live with certain conditions, and those in already good health can greatly benefit from a helping hand of natural cannabinoids found in Kingdom Harvest Ranch & Livestock formula."

On your Facebook and Instagram social media websites at https://www.facebook.com/originalkingdomharvest/ and https://www.instagram.com/kingdomharvest/?hl=en, respectively, for your "Ranch & Livestock Natural Whole-Spectrum Hemp Extract":

- May 7, 2020 Facebook posting and May 6, 2020 Instagram posting with photographs of your "Ranch & Livestock Natural Whole-Spectrum Hemp Extract" next to photographs of a horse, a cow, and an alpaca:
    - "Like humans, our larger Ranch & Livestock pets have Endocannabinoid Systems that help bring balance to their bodies. Introducing a whole-spectrum hemp extract to your horses, cows, alpacas, and any other large variety Ranch & Livestock animals on a daily routine can help promote an overall balance and improved quality of life. Elder Ranch & Livestock Animals & Pets, those that live with certain conditions, and those in already good health can greatly benefit from the helping hand of natural cannabinoids found in Kingdom Harvest Ranch & Livestock formula."

On your Instagram social media website at (https://www.instagram.com/kingdomharvest/?hl=en) for your "Canine Whole-Spectrum Hemp Extract":

- November 27, 2019 posting with a photograph of your "Canine Whole-Spectrum Hemp Extract" with a dog in the background:
    - "Reported benefits include reduction of stress and anxiety, improving mood, pain relief, controlling seizures, and reduction of inflammation."

On your Facebook and Instagram social media websites at https://www.facebook.com/originalkingdomharvest/ and https://www.instagram.com/kingdomharvest/?hl=en, respectively, for your "Feline Chicken Flavor Zero THC Hemp Extract":

- May 8, 2020 posting with a photograph of your "Feline Chicken Flavor Zero THC Hemp Extract" next to a photograph of a cat and photograph of a partially filled medicine dropper held in front of a cat's face:
    - "Reported benefits include reduction of stress and anxiety, improving mood, pain relief, controlling seizures, and reduction of inflammation and many more."

On your product webpage for "Pet Essentials Joint Support Tablets":

- "Pet Essentials CBD Joint Support helps support your pet's joint health through six active ingredients: . . .
    - CBD may help minimize discomfort . . .
    - Chondroitin . . . may help . . . to reduce discomfort . . .

- Turmeric powder has natural properties, which make it a strong anti-inflammatory agent."

On your product webpage for "CBD Infused Pet Shampoo":

- "When used directly on your fur baby's area that you are looking to treat and clean, our CBD Whole-Spectrum PET Shampoo doesn't just clean, soothe, and alleviate irritations. It fights inflammation at the source."

On your product webpage for "CBD Infused Pet Paw Balm":

- "Because CBD PET Paw Balm does not need to be metabolized, a topical dosage is strong, reliable, and starts working quickly. When used directly on the tattooed area that you are looking to treat and protect, our CBD Whole-Spectrum PET Paw Balm doesn't just alleviate irritations. It fights inflammation at the source."

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-1. These products are not approved or index listed by the FDA, and therefore these products 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). The introduction or delivery for introduction of these products 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

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.[9]

Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in animal food is deemed to be unsafe under section 409(a) of the FD&C Act, 21 U.S.C. 348(a), and causes the animal 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 animal 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 that authorizes the use of CBD in animal food. We are not aware of any information to indicate that CBD is the subject of a prior sanction, as described above. Furthermore, we are not aware of any basis to conclude that CBD is GRAS for use in animal foods. FDA's regulations in Title 21, Code of Federal Regulations 570.30(a)-(c), 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.

FDA is not aware of any other exception to the food additive definition that would apply to CBD for use as an ingredient in animal food. Therefore, CBD added to animal 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, 21 U.S.C. 348. 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, 21 U.S.C. 342(a)(2)(C)(i). 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).

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.

According to your product labeling, "Ranch & Livestock Natural Whole-Spectrum Hemp Extract," "Canine Whole-Spectrum Hemp Extract," "Feline Chicken Flavor Zero THC Hemp Extract," and "Pet Essentials Joint Support Tablets," are animal foods to which CBD has been added. Specifically, your website and social media websites refer to these products being mixed into meals ("Ranch & Livestock Natural Whole-Spectrum Hemp Extract" and "Canine Whole-Spectrum Hemp Extract") or intended for consumption based on flavor labeling ("Feline Chicken Flavor Zero THC Hemp Extract" and bacon-flavored "Pet Essentials Joint Support Tablets"). Therefore, the introduction or delivery for introduction into interstate commerce of these products is a prohibited act under section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll).

* * *

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations 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.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action 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 by email to FDAADVISORY@fda.hhs.gov.

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

/S/
Neal Bataller
Director
Division of Drug Compliance
Office of Surveillance & Compliance
Center for Veterinary Medicine
Food and Drug Administration

/S/
Ann M. Oxenham
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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[1] As stated in previous FDA warning letters, the use of untested drugs can have unpredictable and unintended consequences, especially in vulnerable populations. For example, infants may be at greater risk for adverse reactions associated with certain drug products due to differences in the ability of infants to absorb, metabolize, distribute, or excrete such drug products or their metabolites.

[2] There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx. In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://trumpwhitehouse.archives.gov/presidentialactions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

[3] 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 GW Pharmaceuticals Receives Investigational New Drug (IND) From FDA for Phase 2/3 Clinical Trial of Epidiolex(R) 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.

[4] For example, under section 505G of the FD&C Act, 21 U.S.C. 355h, certain nonprescription drug products may be lawfully marketed without an approved application if applicable conditions are met, including conformity with an applicable OTC monograph. However, your products could not be lawfully marketed under section 505G, because based on your claims regarding these products, including on your website labeling, your products are marketed for uses not considered nonprescription indications. Further, even if certain of your products, such as your "Pain Relieving CBD Cream," "Pain Relieving Cream," "CBD & Menthol Pain Freeze Roll-On," and "Stella's Baby Care Diaper Cream," were marketed only for nonprescription indications, they would not meet the conditions under section 505G for lawful marketing without an approved application. For example, CBD—considered an active ingredient under 21 CFR 201.66(b)(2) due to its prominent featuring on your product labeling—is not an active ingredient in any OTC monograph under section 505G of the FD&C Act.

[5] Further, even if your products were marketed only for nonprescription indications, these products would be misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because they would be nonprescription drugs subject to section 505G of the FD&C Act that do not comply with the requirements for marketing under that section (see footnote 1) and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355.

[6] 21 CFR 330.1(e) requires in relevant part that "the product contains only suitable inactive ingredients which are safe in the amounts administered." A suitable inactive ingredient generally provides a beneficial formulation function, such as a tablet binder or preservative, or improves product delivery (e.g., enhances absorption or controls release of the drug substance). CBD has no known functional role as an inactive ingredient in a finished drug product.

[7] Additionally, an inactive ingredient should not exert pharmacological effects and must be safe when used at the intended dosage. CBD has known pharmacological activity with demonstrated risks. For example, the labeling for Epidiolex (cannabidiol) prescription oral solution includes risks for the drug such as liver injury, interactions with other drugs or supplements, potential for male reproductive toxicity, somnolence, insomnia, diarrhea, decreased appetite, abdominal pain, upset stomach, changes in mood, irritability, and agitation. See https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf. It is unknown whether the levels of CBD used in your CBD products have pharmacological activity or pose any concern for safety events.

[8] 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.

[9] 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, 21 U.S.C. § 342(a)(2)(C)(ii).

FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)

Public Health Focus

Accelerating Access to Critical Therapies for ALS Act – ACT for ALS

Infant Formula Information and Ongoing FDA Efforts to Increase Supply

Información sobre la fórmula infantil y los esfuerzos continuos de la FDA para aumentar su suministro

Expanded Access

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01/22/2021

There is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including cannabidiol (CBD). FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products. FDA has a number of resources available that address cannabis and cannabis-derived products, such as CBD, and the agency wants to ensure that consumers and other stakeholders have access to these resources in a centralized location.

Consumer Information

- What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD
- What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding
- Some Medicines and Driving Don't Mix

- 5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC

FDA Communications

- Cannabis-Derived Products Data Acceleration Plan
- Better Data for a Better Understanding of the Use and Safety Profile of Cannabidiol (CBD) Products
- FDA Warns Companies Illegally Selling CBD Products
- FDA Approves New Indication for Drug Containing an Active Ingredient Derived from Cannabis to Treat Seizures in Rare Genetic Disease
- FDA Issues Draft Guidance to Encourage Cannabis-Related Clinical Research
- FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity
- Congressional Testimony: Cannabis Policies for the New Decade
  - Archived Video
- FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns
- Remarks at the Council for Responsible Nutrition Conference
- Remarks at the National Industrial Hemp Council 2019 Hemp Business Summit
- FDA, FTC warn company marketing unapproved cannabidiol products with unsubstantiated claims to treat teething and ear pain in infants, autism, ADHD, Parkinson's and Alzheimer's disease
- Congressional Testimony: Hemp Production and the 2018 Farm Bill
  - Archived Video
- FDA is Committed to Sound, Science-based Policy on CBD
- Remarks at the FDA Public Hearing on Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds
- Statement on new steps to advance agency's continued evaluation of potential regulatory pathways for cannabis-containing and cannabis-derived products
- Statement on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds
- Statement on the importance of conducting proper research to prove safe and effective medical uses for the active chemicals in marijuana and its components
- FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy

Regulatory Resources

- Scientific Conference on November 19, 2020: CBD and Other Cannabinoids: Sex and Gender Differences in Use and Responses
- Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, Draft Guidance for Industry
- Information on CBD Data Collection and Submission
- FDA and Cannabis: Research and Drug Approval Process
- FDA Regulation of Dietary Supplement & Conventional Food Products Containing Cannabis and Cannabis-Derived Compounds
- Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing
  - Federal Register Notice
  - Public Hearing Page
  - Public Docket
- Warning Letters and Test Results for Cannabidiol-Related Products
- State, Local, Tribal, Territorial (SLTT) Regulatory Officials: FDA is committed to working with our SLTT public health regulatory partners as developments occur in the regulatory landscape. Please contact the Intergovernmental Affairs team with any questions at IGA@fda.hhs.gov.

Questions and Answers

Below are a number of frequently asked questions and answers on this topic.

1. What are cannabis and marijuana?
2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?
3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?
4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?
5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?
6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?
7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?
8. Is it legal for me to sell CBD products?
9. Can THC or CBD products be sold as dietary supplements?
10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

Top

1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

3. Has FDA approved any medical products containing cannabis or cannabis-derived compounds such as CBD?

A. To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider.

FDA has approved Epidiolex, which contains a purified form of the drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 1 years of age and older. It has also approved Epidiolex for the treatment of seizures associated with tuberous sclerosis complex in patients 1 year of age or older. That means FDA has concluded that this particular drug product is safe and effective for its intended use.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

4. Aside from Epidiolex, are there other CBD drug products that are FDA-approved? What about the products I've seen in stores or online?

A. No. There are no other FDA-approved drug products that contain CBD. We are aware

that some firms are marketing CBD products to treat diseases or for other therapeutic uses, and we have issued several warning letters to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.

FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

The agency has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process (see Question #16).

5. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective

for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 Guidance for Industry: Botanical Drug Development provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The agency's July 2020 draft guidance, Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry, highlights quality considerations for anyone wishing to conduct clinical research in this area, particularly those who are less familiar with the FDA.

The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the National Cancer Institute (NCI) and National Institute on Drug Abuse (NIDA).

6. What is FDA's reaction to states that are allowing cannabis to be sold for medical uses without the FDA's approval?

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of cannabis and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of cannabis products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of cannabis and its derivatives, so that we can provide information on Federal and scientific standards.

7. Has the agency received any adverse event reports associated with cannabis use for medical conditions?

A. The agency has received reports of adverse events in patients using cannabis or cannabis-derived products to treat medical conditions. The FDA reviews such reports and will continue to monitor adverse event reports for any safety signals, with a focus on serious adverse effects. Consumers and healthcare providers can report adverse events associated with cannabis or cannabis-derived products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088. For more information, please see the FDA's webpage on MedWatch.

Information from adverse event reports regarding cannabis use is extremely limited; the FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using cannabis and its constituents can come from

on the potential adverse effects of using cannabis and its constituents that come from clinical trials that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of cannabis and its constituents is needed. Clinical trials of cannabis conducted under an IND application could collect this important information as a part of the drug development process.

8. Is it legal for me to sell CBD products?

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

9. Can THC or CBD products be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or 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 excluded from the definition of a dietary supplement. 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 FD&C Act.

There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When a substance is excluded from the dietary supplement definition under section

201(ff)(3)(B) of the FD&C Act, the exclusion applies unless FDA, in the agency's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Act. To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of this exclusion, and therefore might be able to be marketed as dietary supplements. However, all products marketed as dietary supplements must comply with all applicable laws and regulations governing dietary supplement products. For example, manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" (i.e., dietary ingredients that were not marketed in the United States in a dietary supplement before October 15, 1994) generally must notify FDA about these ingredients (see section 413(d) of the FD&C Act [21 U.S.C. § 350b(d)]). Generally, the notification must include information demonstrating that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling. A dietary supplement is adulterated if it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury (see section 402(f)(1)(B) of the FD&C Act [21 U.S.C. 342(f)(1)(B)]).

Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

A. No. Under section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which 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 a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not caused us to change our conclusions.

When this statutory prohibition applies to a substance, it prohibits the introduction into interstate commerce of any food to which the substance has been added unless FDA, in the agency's discretion, has issued a regulation approving the use of the substance in the food (section 301(ll)(2) of the FD&C Act [21 U.S.C. § 331(ll)(2)]). To date, no such regulation has been issued for any substance.

Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of 301(ll), and therefore might be able to be added to food. For example, as discussed in Question #12, certain hemp seed ingredients can be legally marketed in human food. However, all food ingredients must comply with all applicable laws and regulations. For example, by statute, any substance intentionally added to food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use, or the use of the substance is otherwise excepted from the definition of a food additive (sections 201(s) and 409 of the FD&C Act [21 U.S.C. §§ 321(s) and 348]). Aside from the three hemp seed ingredients mentioned in Question #12, no other cannabis or cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the food additive and GRAS processes.

11. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution. CBD is the active ingredient in the approved drug product, Epidiolex.

The existence of substantial clinical investigations regarding THC and CBD have been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain)

12. Can hulled hemp seed, hemp seed protein powder, and hemp seed oil be used in human food?

A. In December 2018, FDA completed its evaluation of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. These GRAS notices

related only to the use of these ingredients in human food. To date, FDA has not received any GRAS notices for the use of hemp-derived ingredients in animal food (see Question #25).

Hemp seeds are the seeds of the *Cannabis sativa* plant. The seeds of the plant do not naturally contain THC or CBD. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high."

The GRAS conclusions can apply to ingredients for human food marketed by other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food.

13. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer complaint coordinator. For more information, please see the FDA's webpage on how to report a cosmetic-related complaint.

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?

A. The FDA has sent warning letters in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

15. Can I import or export cannabis-containing or cannabis-derived products?

A. General information about the import/export of drug products regulated by FDA can be found online here. The Drug Enforcement Administration (DEA) is the federal agency responsible for enforcing the controlled substance laws and regulations in the U.S. and, as such, should be consulted with respect to any regulations/requirements they may have regarding the import or export of products containing cannabis. Please see here for information about importing or exporting food ingredients.

Regarding imports, if it appears that an article is adulterated, misbranded, in violation of section 505 of the FD&C Act, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll) of the FD&C Act, such article will be refused admission (see section 801(a)(3) of the FD&C Act [21 U.S.C. § 381(a)(3)]).

Research and Expanded Access

16. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question 10), the 2018 Farm Bill removed hemp from the CSA

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

As also discussed above (see Question #5) the agency also issued a draft guidance in July 2020, Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry, for individuals considering clinical research in this area.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of the IND or INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.
- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also may allow additional growers to register with the DEA to produce and distribute cannabis for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

17. Does the FDA object to the clinical investigation of cannabis for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from cannabis. The FDA supports the conduct of that research by:

1. Providing information on the process needed to conduct clinical research using cannabis.
2. Providing information on the specific requirements needed to develop a drug that is derived from a plant such as cannabis. In December 2016, the FDA updated its Guidance for Industry: Botanical Drug Development, which provides sponsors with guidance on submitting IND applications for botanical drug products.
3. Providing specific support for investigators interested in conducting clinical research using cannabis and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.
4. Providing general support to investigators to help them understand and follow the

procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's Small Business and Industry Assistance group.

18. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?

A. Expanded access is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

19. Can patients gain access to cannabis or cannabis-derived products for medical use through Right to Try?

A. Information for patients on Right to Try (RTT) is available on our website. RTT is designed to facilitate access to certain investigational drugs through direct interactions between patients, their physicians and drug sponsors – FDA is not involved in these decisions. Sponsors developing drugs for life-threatening conditions are responsible for determining whether to make their products available to patients who qualify for access under RTT. If you are interested in RTT, you should discuss this pathway with your licensed physician. Companies who develop drugs and biologics, also known as sponsors, can provide information about whether their drug/biologic is considered an eligible investigational drug under RTT and if they are able to provide the drug/biologic under the RTT Act.

Children and Pregnant/Lactating Women

20. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

21. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of cannabis

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

22. What does the FDA think about making CBD available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 1 years of age and older. It has also approved Epidiolex for the treatment of seizures associated with tuberous sclerosis complex in patients 1 year of age or older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

23. What should I do if my child eats something containing cannabis?

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

Pets and other Animals

24. I've seen cannabis products being marketed for pets. Are they safe?

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA

cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit Reporting Information about Animal Drugs and Devices to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

25. Can hemp be added to animal food?

A. All ingredients in animal food must be the subject of an approved food additive petition or generally recognized as safe (GRAS) for their intended use in the intended species. If an animal food contains an ingredient that is not the subject of an approved food additive petition or GRAS for its intended use in the intended species, that animal food would be adulterated under section 402(a)(2)(C)(i) of the FD&C Act [21 U.S.C. § 342(a)(2)(C)(i)]. In coordination with state feed control officials, CVM also recognizes ingredients listed in the Official Publication (OP) of the Association of American Feed Control Officials (AAFCO) as being acceptable for use in animal food. At this time, there are no approved food additive petitions or ingredient definitions listed in the AAFCO OP for any substances derived from hemp, and we are unaware of any GRAS conclusions regarding the use of any substances derived from hemp in animal food. Learn more about animal food ingredient submissions here.

With respect to products labeled to contain "hemp" that may also contain THC or CBD, as mentioned above it is a prohibited act under section 301(ll) of the FD&C Act to introduce or deliver for introduction into interstate commerce any animal food to which THC or CBD has been added.

26. Can approved human drugs containing CBD or synthetic THC be used extralabel in animals?

A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), permits veterinarians to prescribe extralabel uses of approved human and animal drugs for animals under certain conditions. Extralabel use must comply with all the provisions of AMDUCA and its implementing regulation at 21 CFR § 530. Among other limitations, these provisions allow extralabel use of a drug only on the lawful order of a licensed veterinarian in the context of a valid veterinarian-client-patient relationship and only in

circumstances when the health of an animal is threatened or suffering, or death may result from failure to treat.

In addition, under 21 CFR 530.20, extralabel use of an approved human drug in a food-producing animal is not permitted if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the use. In addition, under 21 CFR 530.20(b)(2), if scientific information on the human food safety aspect of the use of the approved human drug in food-producing animals is not available, the veterinarian must take appropriate measures to ensure that the animal and its food products will not enter the human food supply.
For more information on extralabel use of FDA approved drugs in animals, see Extralabel Use of FDA Approved Drugs In Animals.

[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.

[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.

[7] ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation

top·i·cal (tŏp′ĭ-kəl)

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adj.

1. Being of current interest or relevance: *topical issues.*
2. *Medicine* Relating to, applied to, or affecting a localized area of the body, especially of the skin: *a topical anesthetic.*
3. Of, arranged by, or relating to a particular topic or topics: *a topical concordance to the Bible.*

n.

A topical anesthetic.

[From Greek *topikos*, from *topos*, place.]

top′i·cal′i·ty (-kăl′ĭ-tē) *n.*
top′i·cal·ly *adv.*

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