

This Opinion is a  
Precedent of the TTAB

Mailed: June 16, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE  
Trademark Trial and Appeal Board

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*In re Stanley Brothers Social Enterprises, LLC*

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Serial No. 86568478

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Timothy C. Matson of Fox Rothschild LLP  
for Stanley Brothers Social Enterprises, LLC.

Jeffrey J. Look, Trademark Examining Attorney, Law Office 108,  
Kathy Coward, Managing Attorney.

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Before Wolfson, Adlin and Larkin,  
Administrative Trademark Judges.

Opinion by Adlin, Administrative Trademark Judge:

Applicant Stanley Brothers Social Enterprises, LLC seeks registration of the mark CW, in standard characters, for “hemp oil extracts sold as an integral component of dietary and nutritional supplements.”<sup>1</sup> The record shows that Applicant’s goods contain cannabidiol (“CBD”), an extract of the cannabis plant, that is regulated under the Food, Drug & Cosmetics Act (“FDCA”) as a drug. The Examining Attorney finally refused registration of Applicant’s mark under Sections 1 and 45 of the Trademark Act on the ground that its use in commerce for Applicant’s goods is per se unlawful because the goods are illegal under: (1) the federal FDCA, 21

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<sup>1</sup> Application Serial No. 86568478, filed March 18, 2015 under Section 1(a) of the Trademark Act, alleging first use dates of March 14, 2015.

U.S.C. §§ 321(ff) and 331(ll); and (2) the federal Controlled Substances Act (“CSA”), 21 U.S.C. §§ 812(c) and 841(a)(1).

The Examining Attorney’s refusal based on the FDCA became final first. After Applicant appealed from that refusal and its appeal was fully briefed, the Examining Attorney requested and was granted a remand to also refuse registration based on the CSA. Applicant was then given time to file a supplemental brief addressing the CSA ground for refusal, 13 TTABVUE, but it declined to do so.

### **I. Applicant and Its Goods**

This appeal turns on whether Applicant’s goods are legal under federal law, in particular the FDCA and CSA. That in turn depends on the nature and intended uses of Applicant’s goods.

Applicant is a Colorado marijuana grower owned and operated by the six Stanley brothers. It developed, through crossbreeding, a strain of cannabis which is high in CBD content, and at the same time low in tetrahydrocannabinol (“THC”) content.<sup>2</sup> June 25, 2015 Office Action TSDR 13-24, 32-41. THC is the most psychoactive component of marijuana, and is responsible for the “high” that its users experience, whereas CBD is apparently not psychoactive, and may counteract some of THC’s effects. See September 8, 2017 Office Action TSDR 37-41; August 27, 2016 Office Action TSDR 7-33, 137-139; January 27, 2016 Office Action TSDR 9-41.

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<sup>2</sup> While statutes and other legal materials are not entirely consistent, they tend to use “marijuana” to identify the federally illegal drug produced from the Cannabis sativa L. plant, whereas “hemp” typically refers to the less (or non-) psychoactive and more industrially useful parts of the same plant. We use the terms similarly in this opinion where appropriate given the context, but generally refer to “cannabis” instead.

Oil derived from Applicant’s high CBD/low THC cannabis was found to help Charlotte Figi, a young girl with Dravet Syndrome, a severe form of childhood epilepsy. Specifically, Charlotte’s parents attributed a significant reduction in her seizures to Applicant’s strain of high CBD cannabis. June 25, 2015 Office Action TSDR 13-24, 32-41. Applicant eventually named this strain “Charlotte’s Web,” after Charlotte and the novel of the same name. *Id.* Applicant and its Charlotte’s Web strain were featured in a Sanjay Gupta documentary on CNN, and in related articles. *Id.*

Applicant does not market its CW “hemp extract” as a treatment for childhood epilepsy only, however, but instead claims that it can be used “to promote mind and body wellness” generally:



7/22/2016 Everyday

**EVERYDAY**  
Premium Hemp Extract Supplement  
1000 1000 | Daily Wellness Routine  
**\$39.99 - \$99.99**

Charlotte's Web™ Everyday Dietary Supplement - add to your daily health routine. A great introduction to Charlotte's Web™ proprietary hemp extracts. Add to your everyday healthy routine to promote mind and body wellness and counter daily stresses.

- Non-psychoactive
- Regulates the human endocannabinoid system
- Natural Colorado Wellness™. Grown and made in Colorado, USA

<http://www.cwhemp.com/everyday>

add to cart

**SUGGESTED USE:**  
Adults take two full droppers (approx. 40 drops or 1 mL) approx. two times per day.

Supplement Facts		
Serving Size: 1 mL		
Servings Per Container: 30		
	Amount Per Serving	% Daily Value
Calories	8	
Calories from Fat	8	
Total Fat	1g	2%*
Hemp Extract (aerial parts)	11 mg	**

\* Percent Daily Values are based on a 2,000 calorie diet.  
\*\* Daily Value not established.

Shake well before using. Store in a cool, dry place away from light.

**Not to be used during pregnancy or lactation. If you have a medical condition or take pharmaceutical drugs, please consult your physician before use. Keep out of reach of children.**

**MANUFACTURED BY:**  
CW Hemp  
Boulder, CO 80301  
719-419-8169

Other Ingredients: MCT Fractionated Coconut Oil, Organic Chocolate Mint Flavor Oil (Organic Sunflower Seed Oil, Natural and Organic Flavors).

Everyday Mint Chocolate 100ml

July 22, 2016 Office Action response TSDR 30-36; September 8, 2017 Office Action TSDR 77-79 (“The Stanley brothers are now targeting a much broader market, the health and wellness market, and have rebranded as CW Hemp.”).

## **II. Industrial Hemp, CBD’s Legal Status, and Applicant’s Authorization from the Colorado Department of Agriculture**

Under the CSA, marijuana is a Schedule I controlled substance, and is thus illegal to “manufacture, distribute, or dispense.” 21 U.S.C. § 841(a)(1). “Marijuana” is defined in the CSA as:

all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

21 U.S.C. § 802(16)(A).<sup>3</sup>

Applicant’s responses to the Examining Attorney’s information requests under Trademark Rule 2.61(b), 37 C.F.R. § 2.61(b), establish that Applicant’s CW hemp oil extract falls within this definition of “marijuana.” March 8, 2018 Office Action response TSDR 15 (Applicant’s hemp oil is “obtained from resins extracted from ... the *Cannabis sativa* L. plant, including ... the ... leaves, flowering tops, buds or seeds” thereof); *see also* September 8, 2017 Office Action TSDR 77-79. Moreover, the information provided on the CW product’s packaging, reproduced above, indicates that Applicant’s “hemp extract” comes from “aerial parts” of the plant.

In the Agricultural Act of 2014 (the “2014 Farm Bill”), however, Congress excepted “industrial hemp” from some of the CSA’s prohibitions, under certain circumstances:

### **Legitimacy of industrial hemp research**

#### **(a) In general**

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<sup>3</sup> As discussed below, an exception to the definition of “marijuana” was added to the CSA in 2018. 21 U.S.C. § 802(16)(B).

Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), chapter 81 of title 41, or any other Federal law, an institution of higher education (as defined in section 1001 of title 20) or a State department of agriculture may grow or cultivate industrial hemp if—

(1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and

(2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

**(b) Definitions** In this section:

(1) **Agricultural pilot program** The term “agricultural pilot program” means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

(A) in States that permit the growth or cultivation of industrial hemp under the laws of the State; and

(B) in a manner that (i) ensures that only institutions of higher education and State departments of agriculture are used to grow or cultivate industrial hemp; (ii) requires that sites used for growing or cultivating industrial hemp in a State be certified by, and registered with, the State department of agriculture; and (iii) authorizes State departments of agriculture to promulgate regulations to carry out the pilot program in the States in accordance with the purposes of this section.

(2) **Industrial hemp** The term “industrial hemp” means the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

(3) **State department of agriculture** The term “State department of agriculture” means the agency, commission, or department of a State government responsible for

agriculture within the State.

7 U.S.C. § 5940 (the “Industrial Hemp Provision”).

Applicant indicated in responses to information requests that its CW hemp oil extract has a THC concentration of not more than 0.3 percent. March 8, 2018 Office Action response TSDR 15 (“Applicant’s hemp oil meets the qualification for being lawful under the CSA and the 2014 Farm Bill.”); July 21, 2016 Office Action response TSDR 13 (the industrial hemp from which Applicant’s goods are manufactured has a THC “concentration of less than 0.3 percent on a dry weight basis”). Accordingly, Applicant’s goods appear to include CBD derived from cannabis which falls within the Industrial Hemp Provision’s definition of “industrial hemp.” 7 U.S.C. § 5940(b)(2) (defining “industrial hemp” as “the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis”).

Moreover, Applicant introduced official records showing that the Colorado Department of Agriculture authorized Applicant to grow industrial hemp in several locations:





305 Interlocken Parkway, Broomfield, CO 80021  
P 303.869.9050 F 303.496.2860  
[www.colorado.gov/dpa](http://www.colorado.gov/dpa)

THIS DOCUMENT IS NOT TRANSFERABLE

CWB Holdings, Inc.  
CW Botanicals  
18100 CR KK  
Wray, CO 80758

INDUSTRIAL HEMP REGISTRATION - # 66783

Pursuant to § 35-61-102, C.R.S., the above named person / business is authorized to act as:

Outdoor Commercial Industrial Hemp Registration  
36 Acres

Issued  
April 22, 2016

Expires  
April 21, 2017

Don Brown  
Commissioner of Agriculture

April 22, 2016  
Print Date

July 21, 2016 Office Action response TSDR 18-20. Applicant confirmed, in response to information requests, that its cannabis is “grown or cultivated ... for purposes of research conducted under the agricultural academic research program from a university or state department of agriculture.” *Id.* at 13. Applicant also submitted an e-mail from the Colorado Department of Agriculture’s Director, Division of Plant Industry, stating that under Colo. Rev. Stat. § 35-61-108(2), Applicant may “process, sell or distribute hemp ... and can also sell hemp products ....” According to the Director, the state statute “seems to cover all of the areas the Stanley’s [sic] would need for their hemp oil market study.” *Id.* at 21.

The Industrial Hemp Provision was subject to competing interpretations by government agencies, the cannabis and hemp industries, and others. *See, e.g.*, January 27, 2016 Office Action TSDR 9-41. Apparently as a result, Congress included related provisions in subsequent appropriations bills. One typical version is as follows:

SEC. 729. None of the funds made available by this Act or any other Act may be used—

(1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) [i.e., the Industrial Hemp Provision]; or

(2) to prohibit the transportation, processing, sale, or use of industrial hemp, or seeds of such plant, that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.<sup>4</sup>

Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, 132 Stat. 348 § 729.<sup>5</sup>

Later, on December 20, 2018, after Applicant’s appeal was fully briefed and ready for decision, the 2018 Farm Bill – which expands on the Industrial Hemp Provision – became law. Under the 2018 Farm Bill, “hemp” is now 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.**” 7 U.S.C. § 1639o (emphasis added). Perhaps more

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<sup>4</sup> This statute is in many ways analogous to the appropriations riders discussed in *In re PharmaCann LLC*, 123 USPQ2d 1122, 1123 (TTAB 2017). As we pointed out in *PharmaCann*, this type of appropriations rider does not make marijuana or any particular industrial hemp-related goods legal.

<sup>5</sup> In his request for remand, the Examining Attorney indicated that he withdrew the original CSA refusal based on Applicant’s “representation that the goods were in compliance with the 2014 Farm Bill, 7 USC Section 5940.” After the DEA added “marijuana extract” to the list of substances covered by the CSA, the Examining Attorney sought to reinstate the CSA refusal. According to the “Clarification of the New Drug Code (7350) for Marijuana Extract” page from the DEA’s website cited by the Examining Attorney, however, the Final Rule adding the new drug code 7350 for marijuana extract “did not add any substance to the schedules that was not already controlled, and did not change the schedule of any substance. It was not a scheduling action under 21 U.S.C. §§ 811 and 812.” 10 TTABVUE 6. In other words, according to the DEA, “marijuana extract” was already a controlled substance under the CSA.

importantly, the CSA was amended to specifically exclude “hemp, as defined in section 1639o of title 7” from the definition of “marijuana.” 21 U.S.C. § 802(16)(B)(i).<sup>6</sup>

### III. Analysis

Before considering the Industrial Hemp Provision’s (and 2018 Farm Bill’s) impact, if any, on the refusal, we first consider the standards governing unlawful use refusals generally.

#### A. Refusals Based on Unlawful Use

“[U]se of a mark in connection with unlawful shipments in interstate commerce is not use of a mark in commerce which the Patent [and Trademark] Office may recognize.” *Coahama Chem. Co., Inc. v. Smith*, 113 USPQ 413, 418 (Comm’r. Pat. 1957), *aff’d on other grounds*, 264 F.2d 916, 121 USPQ 215 (CCPA 1959). Accordingly, “[w]e have consistently held that, to qualify for a federal ... registration, the use of a mark in commerce must be ‘lawful.’” *PharmaCann*, 123 USPQ2d at 1123 (quoting *In re JJ206, LLC*, 120 USPQ 1568, 1569 (TTAB 2016) and *In re Brown*, 119 USPQ2d 1350, 1351 (TTAB 2016)). In *PharmaCann*, *JJ206* and *Brown* we affirmed unlawful use refusals to register marks used for marijuana-related products or services. As specifically held in *JJ206*, “where the identified goods are illegal under the federal Controlled Substances Act (CSA), the applicant cannot use its mark in lawful commerce ...” 120 USPQ2d at 1569.

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<sup>6</sup> As explained in the USPTO’s recent Examination Guide entitled “Examination of Marks for Cannabis and Cannabis-Related Goods and Services after Enactment of the 2018 Farm Bill” (Exam Guide 1-19), “[f]or applications filed on or after December 20, 2018 that identify goods encompassing cannabis or CBD, the 2018 Farm Bill potentially removes the CSA as a ground for refusal of registration, but **only** if the goods are derived from ‘hemp.’”

However, the USPTO's longstanding practice has been to presume a mark's use in commerce is lawful unless the application record indicates a violation of federal law. *See, e.g., In re Brown*, 119 USPQ2d 1350, 1351 (TTAB 2016).

Due to a proliferation of federal regulatory acts in recent years, there is now an almost endless number of such acts which the Board might in the future be compelled to interpret in order to determine whether a particular use in commerce is lawful. Inasmuch as we have little or no familiarity with most of these acts, there is a serious question as to the advisability of our attempting to adjudicate whether a party's use in commerce is in compliance with the particular regulatory act or acts which may be applicable thereto. **Rather, it seems that the better practice would be to hold that a use in commerce is unlawful only when the issue of compliance has previously been determined (with a finding of noncompliance) by an entity, such as a court or government agency, having competent jurisdiction under the statute in question, or when there has been a per se violation of a statute regulating the sale of a party's goods, or the rendering of his services, in commerce,** as, for example, when a regulatory statute requires that a party's labels must be registered with or approved by the regulatory agency charged with administering the statute before his goods may lawfully enter the stream of commerce, and the party has failed to obtain such registration or approval (as happened in the Coahoma case).

*Satinine Societa v. P.A.B. Produits*, 209 USPQ 958, 964 (TTAB 1981) (emphasis added); *In re Stellar Int'l, Inc.*, 159 USPQ 48, 51 (TTAB 1968) ("This does not mean that the Patent Office should undertake to police all the different regulatory statutes to ensure compliance therewith for that is manifestly not its function nor is it properly equipped to do so."); *see also Gen. Mills Inc. v. Health Valley Foods*, 24 USPQ2d 1270 (TTAB 1992); *Kellogg Co. v. New Generation Foods Inc.*, 6 USPQ2d 2045, 2047 (TTAB

1988). We recently summarized the applicable standard:

[R]egistration generally will not be refused based on unlawful use in commerce unless either (1) a violation of federal law is indicated by the application record or other evidence, such as when a court or a federal agency responsible for overseeing activity in which the applicant is involved, and which activity is relevant to its application, has issued a finding of noncompliance under the relevant statute or regulation, or (2) when the applicant's application-relevant activities involve a per se violation of a federal law.

*Brown*, 119 USPQ2d at 1351 (citing *Kellogg Co.* and *Satinine*).

### **B. The FDCA Refusal**

The FDCA prohibits “[t]he introduction or delivery for introduction into interstate commerce of any food to which has been added ... a drug or biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public ...” 21 U.S.C. § 331(l). The Examining Attorney contends that Applicant’s “hemp oil extracts” are food to which CBD has been added, and that CBD was the subject of clinical investigations during prosecution of the involved application.

Applicant makes three counterarguments. First, Applicant asserts that the 2014 Farm Bill’s Industrial Hemp Provision exempts it from this portion of the FDCA. Second, Applicant argues that its goods do not fall within the cited prohibition because they are “dietary supplements” rather than food. Finally, Applicant argues that CBD falls within an FDCA exception for drugs or biological products “marketed in food ... before any substantial clinical investigations involving the drug or the biological product have been instituted.” 21 U.S.C. § 331(l)(1). Applicant’s arguments

are not well taken.

Applicant's argument that the Industrial Hemp Provision exempts it from this portion of the FDCA is misplaced. The Industrial Hemp Provision permits authorized entities to "grow or cultivate industrial hemp" under certain circumstances, but it does not permit the distribution or sale of CBD in food when CBD is the subject of clinical investigation, **even if** the CBD is derived from industrial hemp which falls outside the CSA. As the Examining Attorney points out,

the FDCA does not prohibit or interfere with applicant's growing or cultivation of industrial hemp. Applicant is free under the cited FDCA provisions to grow as much industrial hemp as it wants to and is otherwise permitted under the laws of Colorado. What the FDCA does prohibit is the selling in interstate commerce of a food or dietary supplement product to which has been added a botanical compound that is under clinical investigation as a new drug ... In other words, it is not the industrial hemp to which the FDCA applies, but the CBD cannabinoid oil extracted from the hemp.<sup>7</sup>

6 TTABVUE 12. Thus, while the Industrial Hemp Provision is a limitation on the CSA under certain circumstances, it does not override the FDCA's prohibition on offering "food to which has been added ... a drug or biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."<sup>8</sup> The same logic would apply under the

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<sup>7</sup> Under 21 U.S.C. § 321(ff) "a dietary supplement shall be deemed to be a food within the meaning of this chapter."

<sup>8</sup> Because there is no conflict between the Industrial Hemp Provision and the FDCA, Applicant's argument based on the Consolidated Appropriations Act of 2018 and its predecessors is not well taken. The prohibition on spending funds to enforce laws "in contravention of" the Industrial Hemp Provision is inapplicable to the FDA's enforcement of the FDCA. Similarly, the 2018 Farm Bill does not restrict the FDA's enforcement of the

2018 Farm Bill, which as indicated became law after this appeal was briefed.

Turning to the substantive question under 21 U.S.C. § 331(l), Applicant's goods fall within the FDCA's definition of "food." Under 21 U.S.C. § 321(f), "[t]he term 'food' means (1) articles used for food or drink for man or other animals ... and (3) articles used for components of any such article." Applicant's goods are intended to be "food or drink for man," or "articles used for components" of "food or drink for man," as they are recommended to be used in recipes for beverages, offered in "multiple flavors" (including mint chocolate) and promoted as "dietary supplements":

CHARLOTTE'S WEB™ ADV



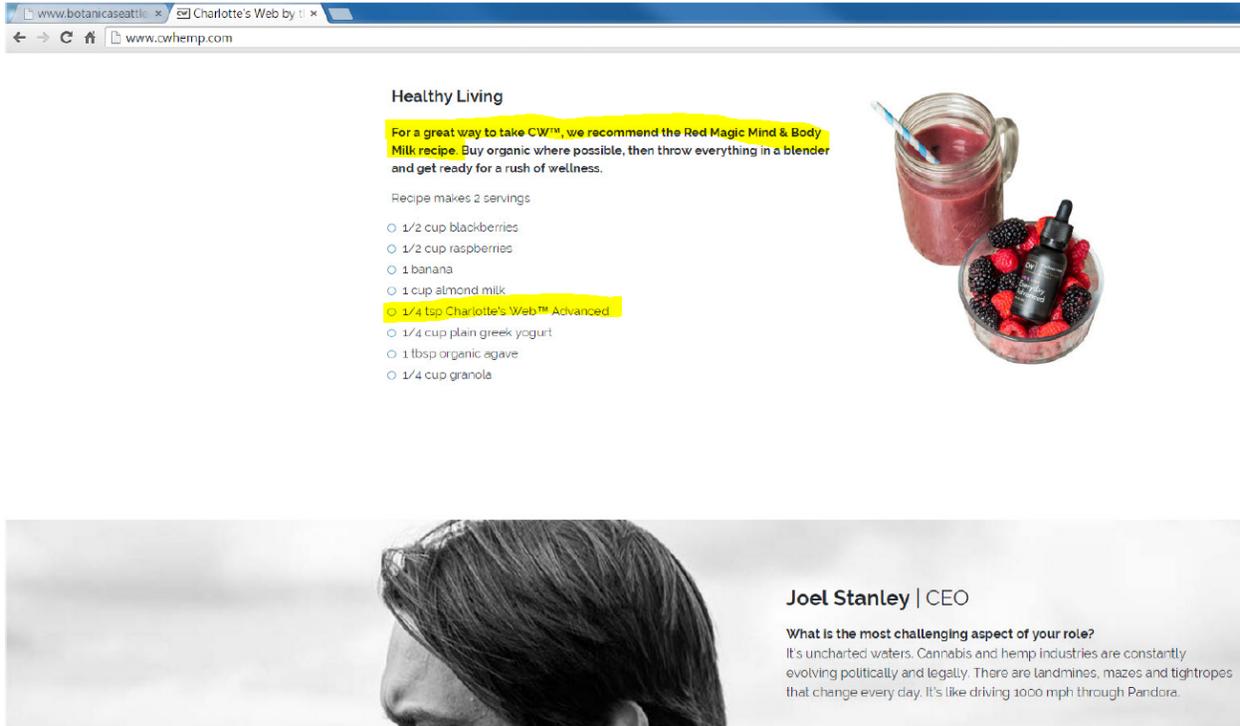
000 200  
**EVERYDAY**  
([HTTP://WWW.CWHEMP.COM/EVERYDAY](http://www.cwhemp.com/everyday))  
**\$39.99 - \$99.99**  
Multiple flavors & sizes available



**EVERYDAY**  
Premium Hemp Extract Supplement  
000 200 Daily Recommended Dose  
**\$39.99 - \$99.99**

Charlotte's Web™ Everyday Dietary Supplement - Add to your daily health routine. A great introduction to Charlotte's Web™ proprietary hemp extracts. Add

FDCA.



June 25, 2015 Office Action TSDR 5; August 27, 2016 Office Action TSDR 49; July 22, 2016 Office Action response TSDR 44; Substitute Specimen submitted July 22, 2016. Moreover, because Applicant identifies its goods as “an integral component of dietary and nutritional supplements,” they are “deemed to be a food within the meaning of this chapter.” 21 U.S.C. § 321(ff) (“a dietary supplement shall be deemed to be food within the meaning of this chapter”).

The CBD in Applicant’s goods qualifies as a “drug or biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public” under 21 U.S.C. § 331(ll). Indeed, the FDA specifically cites “GW Pharmaceuticals’ investigations regarding Sativex and Epidolex” in support of its position that CBD, found in Applicant’s “hemp oil extracts,” is under “substantial clinical investigations.” August 27, 2016 Office Action TSDR 52-

57; July 22, 2016 Office Action response TSDR 37-40. According to the FDA, “[t]he general rule is that an article that has been authorized for investigation as a new drug or as a biologic before being marketed as a food or as a dietary supplement cannot be marketed as a dietary supplement if substantial clinical investigations of the article have begun and the existence of such investigations has been made public.”

August 27, 2016 Office Action TSDR 60-114. Therefore, Applicant’s goods fall within 21 U.S.C. § 331(ll) and are unlawful under the FDCA.

Applicant’s third counterargument, that its goods fall within the FDCA’s exception for drugs or biological products “marketed in food ... before any substantial clinical investigations involving the drug or the biological product have been instituted,” under 21 U.S.C. § 331(ll)(1), is unsupported by any probative evidence. Indeed, the only purported evidence Applicant cites in support of this argument is the following statement from the Hemp Industries Association (“HIA”) in a press release:

It is the position of the HIA that legal hemp products containing CBD were marketed as foods and dietary supplements long before cannabidiol formulations were submitted to the FDA for testing as a “new drug.” As such, CBD products are exempt from laws that preclude CBDs from product status as dietary supplements pending “new drug” approval by the FDA.

July 22, 2016 Office Action response TSDR 41. The record contains no evidence supporting this self-styled “position,” and the FDA disputes it. August 27, 2016 Office Action TSDR 52-59.

We do not find the HIA press release persuasive here. It references a letter which

HIA sent to the FDA, but Applicant failed to introduce the letter itself into the record, or, more to the point, any underlying evidence supporting the letter or HIA's position. A trade group's unadorned statement of a "position" (as opposed to fact), unsupported by any evidence, is an insufficient basis upon which to make a finding of fact, especially where the FDA disputes the stated position. That is especially true in this case, where the ingredient in question, CBD, is primarily derived from cannabis, which was illegal under federal law in all or almost all forms for decades prior to 2014, and remains illegal under federal law in many if not all forms today.<sup>9</sup> Therefore, Applicant's goods are per se unlawful under 21 U.S.C. § 331(l).

#### **IV. Conclusion**

The Examining Attorney has established a per se violation of the FDCA, because: Applicant's goods are food to which has been added a drug (CBD); substantial clinical investigations of CBD have been instituted, and the existence of these investigations has been made public; and there is no evidence of record that CBD was marketed in food before the substantial clinical investigations of CBD were instituted. We need not reach the unlawful use refusal based on the CSA. *In re Mueller Sports Med., Inc.*, 126 USPQ2d 1584, 1590 (TTAB 2018).

**Decision:** The unlawful use refusal based on the FDCA is affirmed.

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<sup>9</sup> To the extent Applicant argues that its goods are "dietary supplements" and therefore not subject to the FDCA provisions cited by the Examining Attorney, it is incorrect. 21 U.S.C. § 321(ff)(3)(B)(ii) (dietary supplements do not include "an article 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, which was not before such approval ... marketed as a dietary supplement or as a food.").