

# IP HOT TOPIC

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## **FDA Expedites its Efforts to Release CBD Regulations**

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By: [Pauline M. Pelletier](#)

Products containing cannabidiol (“CBD”), a compound derived from cannabis, are part of a growing market that some analysts have projected will reach over \$2.3 billion by 2022.<sup>[1]</sup> CBD products—from gummy bears and pet products to cosmetics and shoe polish—are cropping up everywhere and industries, from biopharma to beer, are paying attention.<sup>[2]</sup> Here we provide an update on how CBD products may be regulated and how this will impact cannabis trademarks.

We will be exploring this topic and others relating to cannabis intellectual property in an upcoming Strafford live webinar, “Protecting Cannabis IP” on Tuesday, August 20, 1:00pm-2:30pm ET. For more information, please [click here](#).

### Hemp Legalization and the CBD Boom

CBD products are popular in nearly every age group (from teens to baby boomers) and for a wide range of uses (from recreation to joint pain). Despite its viral popularity, the question remains: are CBD-containing products legal? With the passage of the 2018 Farm Bill, hemp-derived CBD is no longer subject to the Controlled Substances Act (CSA), but how it will be regulated by the Food & Drug Administration (FDA) and other agencies remains in flux. Facing pressure from legislators, federal agencies have now started in earnest to craft CBD regulations.<sup>[3]</sup>

The 2018 Farm Bill defines “hemp” as cannabis plants and derivatives containing no more than 0.3% THC on a dry weight basis. This means that cannabis plants and derivatives meeting this definition are no longer considered controlled substances under federal law. While the Farm Bill strictly limits the amount of THC that can be present in the plant, the law does not limit the amount of other cannabinoids that may be present in hemp, including the ultra-popular cannabis derivative CBD. This recent change in the law has opened the door to federal trademark protection for products and services that involve CBD that is derived from legally-produced hemp.

Rapidly growing interest in CBD spurred the FDA to hold its first public hearing on CBD regulation in May of 2019. On July 12, 2019, the FDA’s Acting Chief Information Officer, Amy Abernethy, tweeted that “FDA is expediting its work to address the many questions about cannabidiol (CBD),” describing it as “an important national issue with public health impact,” further noting that “[w]e plan to report on our progress around end of summer/early fall.”<sup>[4]</sup> The Department of Agriculture (USDA) also stated that it plans to issue interim final rules in August.

## Eligibility for Federal Trademark Protection

The availability of federal trademark protection in this space is substantially intertwined with the legal status of cannabis, including how hemp-derived CBD will be regulated by federal agencies like the FDA. This is because the Patent & Trademark Office (PTO) generally refuses to register trademarks on products and services that lack a “legal use” of the mark in commerce. Historically, this prohibition has made federal trademark protection largely unavailable for many cannabis-related products and services. Passage of the Farm Bill changed this, however, opening the door to federal trademark protection for products and services related to hemp-derived CBD.[5]

Even though “hemp” is no longer considered a controlled substance under federal law, the PTO still looks to related regulatory frameworks, including FDA regulations and policies promulgated pursuant to its authority under Food Drug and Cosmetic Act (FDCA).[6] In other words, to be eligible for federal trademark protection, products and services must be legal under federal law as that law has been interpreted by the federal agencies charged with enforcing them.

## FDA Regulation of CBD-Containing Products

Following the FDA’s public hearing in May, the agency has announced that it plans to expedite its internal process for rolling out CBD regulations. Thus, it seems inevitable that the FDA will regulate CBD in the near-term, but how comprehensively still remains unclear. The FDA has already reviewed and approved CBD as a “drug” through its assessment of Epidiolex, which was approved in 2018 for the treatment of two rare forms of epilepsy. To date, the FDA has not expressly endorsed any other pathways for approval. Rather, the agency has stated only that CBD cannot be used as a food additive or dietary supplement and that it will be exercising its discretionary enforcement authority against those making false or misleading health claims.[7]

This regulatory uncertainty has left many stakeholders wondering whether and when they can legally market their products. This in turn impacts whether those products and services are eligible for federal trademark protection. We are closely tracking these developments and will continue to issue updates as the FDA and USDA clarify their positions.

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[1] Stakeholders Await the FDA’s First Public Hearing About Cannabis and CBD, New Frontier Data (May 29, 2019) ([link](#)).

[2] Hemp Legalization and the International CBD Boom ([link](#)).

[3] Lawmakers grow impatient for FDA cannabis rules, The Hill (Jul. 6, 2019) ([link](#)).

[4] @DrAbernethyFDA (12:44 PM - 12 Jul 2019) ([link](#)).

[5] Trademark Registration Sees a New High: Registration for trademarks for goods derived from “hemp” now allowed under USPTO rules ([link](#)).

[6] IP’s Developing Role In Cannabis Business Strategy ([link](#)); Are Cosmetic Products Containing Hemp-Derived CBD On a Faster Track To Being Lawful? ([link](#)); Up in Smoke? IP Protection for Cannabis Products ([link](#));

[7] Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency’s regulation of products containing cannabis and cannabis-derived compounds (Dec. 20, 2018) ([link](#)).

**For more information, please contact:**



**Pauline M. Pelletier**

Director

[ppelletier@sternekessler.com](mailto:ppelletier@sternekessler.com)

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