State, Federal Disconnect Sows Confusion For CBD Industry

By **Andrew Kingsdale, Lauren Mendelsohn and Omar Figueroa** (February 21, 2023)

Andrew Kingsdale

Lauren Mendelsohn

Omar Figueroa

Despite the U.S. Food and Drug Administration's recent announcement punting on hemp-derived CBD rules for use in dietary supplements and foods,[1] the agency has not abdicated its role interpreting and enforcing laws related to hemp-derived CBD.

To the contrary, the agency's Jan. 26 announcement makes clear that the FDA "will remain diligent in monitoring the marketplace, identifying products that pose risks and acting within [its] authorities."

The announcement generally stated that the existing legal framework governing food and dietary supplements is insufficient to manage certain risks associated with CBD, and therefore Congress would have to step in.

Nevertheless, the FDA has continued to issue warning letters to CBD-product manufacturers, with renewed focus on CBD products that constitute or mimic conventional foods.

An FDA article released concurrently with its announcement highlights the FDA's heightened concern that certain traditional food forms may be attractive to children and confusing to vulnerable populations, "result[ing] in accidental consumption or overconsumption of CBD." The article notes:

> This is particularly true for CBD containing products in forms that are appealing to children, such as gummies, hard candies and cookies. Many of these products can easily be mistaken for conventional foods that are commonly consumed by children and may cause harm.[2]

This article states that while safe dosages of CBD remain uncertain, the FDA has collected evidence of real risks from consuming CBD in general, including risks of liver injury, harm to reproductive systems, side effects and drug interactions.

The FDA is especially concerned about potential risks to sensitive or vulnerable populations, such as children and people who are pregnant, breastfeeding and/or taking other medications.

But in the absence of more permissive federal regulations, states have stepped in to fill the void, creating confusion for CBD industry stakeholders and consumers. This disconnect will ultimately need to be resolved by congressional action.

Recent FDA Warning Letters Underscore the New Focus on Conventional Foods

The FDA has a long history of issuing warning letters to CBD manufacturers.[3] Over the past couple of years, the FDA has clamped down on companies claiming their CBD can help cure or treat COVID-19.

But recent FDA warning letters highlight the FDA's renewed focus on data indicating that CBD may be harmful to vulnerable populations in general.

On the one hand, it is not unusual for the FDA to target foods marketed or intended for use by children,[4] or to target products that mimic the packaging of well-known food products commonly marketed to children.[5]

Also, these recent warning letters continue the FDA's long-standing position that infusing foods or supplements with CBD violates the Food, Drug and Cosmetics Act.

The FDA deems CBD-infused foods to be adulterated because the agency has never approved CBD as a food additive.[6] Unless a food additive is generally recognized as safe among qualified experts under the conditions of its intended use, or unless the substance meets certain exceptions and receives FDA premarket approval,[7] then the additive is deemed unsafe, and the product is adulterated.

For years, the FDA has maintained that there is no basis to conclude that CBD — other than that which is present in hemp seed oil, hulled hemp seeds and hemp seed protein powder — is generally recognized as safe for use in conventional foods, and no other exceptions apply. Therefore, any food to which CBD has been added may not be introduced into interstate commerce.[8]

Nevertheless, these recent rounds of warning letters stand out as targeting particular conventional food form factors — apparently deemed per se attractive to children, and therefore meriting heightened regulatory attention.

For example, CBD-infused gummies, fruit snacks, gum, candy and lollipops triggered concern, as the FDA indicated in one warning letter:

> The use of untested drugs [in those foods] can have unpredictable and unintended consequences, especially in vulnerable populations, such as children. For example, children may be at greater risk for adverse reactions associated with certain drug products due to differences in the ability of children to absorb, metabolize, distribute, or excrete such drug products or their metabolites.[9]

Other food types singled out by the FDA include CBD-infused cookies, hard candies and dried fruit because they are traditional foods attractive to children and risk unintended consumption of CBD.[10]

Additionally, some adult beverage form factors, such as CBD sparkling tea, CBD sparkling water and CBD coffee attracted the FDA's attention as potential vehicles for accidentally overconsuming CBD.[11]

Caffeinated products are of particular concern because "[e]vidence suggests that CBD may affect caffeine metabolism and may increase and/or prolong caffeine's effects."[12]

Focus on Gummies May Be Particularly Disruptive to the Industry

CBD manufacturers should pay particular attention to the FDA's treatment of gummies. Gummies are both a popular form of CBD-infused products, and also a form that straddles the distinction between dietary supplement and conventional food.

Under the FD&C Act, dietary supplement forms typically include tablets, capsules, powders,

softgels, gelcaps or liquid forms, or at least are not represented to consumers as conventional food.[13]

The FDA does not permit any amount of CBD in dietary supplements or conventional foods; nevertheless, if the FDA classifies a gummy as conventional food — e.g., a candy — then the agency may be more concerned about potential overconsumption and attractiveness to children, and therefore be more likely to issue a warning letter regarding products in gummy form.

In the recent warning letters, the FDA determined that certain gummies were conventional foods with CBD additives, as opposed to supplements, based on two factors.

First, if a gummy product bears a nutritional panel — as opposed to a supplement panel — or is marketed with nutrition information, that indicates it is a traditional food with CBD additives.

Second, if a product's marketing implies it is to be consumed like a food or a candy, then again it is more likely to be considered a conventional food and attract the FDA's attention.

For example, according to one warning letter, a manufacturer claimed its gummies were "'the perfect way to satisfy your sweet tooth.'"[14] Another promoted its gummies as "'like classic gummy bears ... one of the most popular candy treats on the planet. People love the burst of flavor that comes with these delicious chews.'"[15]

Aside from the fact that children and vulnerable populations are more prone to overconsume CBD in conventional food compared to in dietary supplements such as tinctures and capsules, characterizing gummies as conventional foods also affects manufacturing safety standards and protocols.

For example, conventional food manufacturers must conduct certain hazard analyses, implement preventive controls and develop a supply-chain program, whereas dietary supplement manufacturers are generally exempt from these regulatory requirements.[16]

Similarly, conventional food additives require premarketing FDA approval or ingredients that are generally recognized as safe — requirements that do not apply to dietary supplements.[17]

States Blaze Different Pathways for the Regulation of CBD and Other Cannabinoids

The FDA's renewed focus on CBD-infused conventional foods further exposes a disconnect between state and federal regulation, and could lend to increased marketplace confusion.

In the absence of clear federal rules, approximately half of the states have developed regulations that specifically allow the use of CBD in dietary supplements and/or traditional food product forms, such as candies and caffeinated beverages.

These states use a variety of strategies to protect consumers, such as limiting the amount of CBD per serving and per package; requiring health warnings about vulnerable consumers like children and pregnant women; and prohibiting marketing, advertising and labeling that may be attractive to children.

For example, New York's cannabinoid hemp regulations limit food and beverage products to no more than 25 milligrams of total cannabinoids, and limit supplements to no more than

100 milligrams per serving.

The regulations also prohibit cannabinoid hemp product packaging that imitates a candy label or uses images popularly used to advertise to children, and require packaging to contain certain warning statements, such as "keep out of the reach of children."[18]

States also set strict guidelines for how CBD products are manufactured. In California and numerous other states, CBD product manufacturers must comply with good manufacturing practices, and all hemp extract must be tested by an independent laboratory prior to being incorporated into a product.[19]

These commonsense restrictions give cannabinoid hemp manufacturers clear guidelines to follow. Unfortunately, the FDA does not appear to factor in CBD amounts, product labeling or warnings, or manufacturing processes. It has opted to use a bludgeon — a per se prohibition based on product type — rather than more nuanced regulations.

If the FDA instead followed the model of some states, taking an approach that factors in CBD amounts, for example, it would disincentivize CBD companies from maximizing the CBD in their products in response to perceived consumer demand for high-potency products.

Of course, there are significant differences between how states regulate ingestible CBD products as well. Congress and the FDA will have evidence and data from these laboratories of democracy — such as adverse events resulting from products manufactured and labeled pursuant to different standards — to craft a more nuanced approach.

Pathway Forward for Federal Regulation?

The persistent divergence between federal and state regulation of CBD products creates turmoil and confusion within the CBD industry.

Responses to the Nov. 16, 2022, warning letters — obtained through a Freedom of Information Act request — indicate that these manufacturers were unaware of the FDA's rules and/or confused by the conflict with state law.

One Florida manufacturer, Naturally Infused LLC, responded, "I was under the impression that since the 2018 Farm Bill all products associated with hemp we're [sic] legal. I was never aware of any interstate commerce regulations with hemp products."

What is a better pathway forward for federal regulation of cannabidiol products? Geoff Whaling, chair of the National Hemp Association, told us in an email that any federal standards for consumable CBD products "need to include strict adherence to growing and processing standards, proper verifiable labeling, and dosing."

He also noted that "at the same time Congress also should address access to capital from the private sector and fund research for the hemp industry."

Hopefully Congress, armed with adequate evidence-based facts about safe levels of CBD, can build out a comprehensive set of rules for the CBD consumables industry. And in the meantime, states will continue to fill the void.

In the 2023 Farm Bill, Congress should allocate funds to adequately research the safety and effectiveness of CBD as well as other hemp-derived cannabinoids, research that the FDA

repeatedly has stated is lacking.

Given high consumer demand for CBD products, the FDA should expedite this research rather than wait for industry stakeholders to conduct it, and then help Congress to craft the evidence-based regulatory framework that is needed according to its Jan. 26 announcement.

Correction: A previous version of this article misstated the maximum amount of cannabinoid milligrams per serving permitted in supplements under New York's regulations. The error has been corrected.

Andrew Kingsdale is of counsel at the Law Offices of Omar Figueroa.

Lauren Mendelsohn is a senior associate at the Law Offices of Omar Figueroa. She serves on the board of directors of California NORML, the state chapter of the National Organization for the Reform of Marijuana Laws.

Omar Figueroa is the founder and principal of the Law Offices of Omar Figueroa. He serves on the board of directors of the National Cannabis Industry Association and the Cannabis Travel Association International.

[1] "FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward," https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol.

[2] FDA, "What the FDA is Doing to Protect Consumers from Cannabidiol (CBD) in Foods," Nov. 21, 2022, https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-cannabidiol-cbd-foods.

[3] FDA, "Warning Letters and Test Results for Cannabidiol-Related Products," https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products.

[4] See, e.g., November 22, 2019 warning letter to CDRL Nutritional, Inc. regarding "CBD Softgels for Kids, 10 mg."

[5] See, e.g., FDA, "FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC," June 16, 2022, https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc.

[6] See FDA, "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)," https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#food (last visited February 6, 2023).

[7] See section 201(s) of the FD&C Act [21 U.S.C. 321(s).

[8] See section 301(ll) of the FD&C Act, 21 U.S.C. 331(ll).

[9] Nov. 16, 2022 Warning Letter to Infusionz Inc.

[10] Nov. 16, 2022 warning letter to Newhere Inc dba CBDFX; December 5, 2022 warning letter to Thriftmaster Texas, LLC. d/b/a ThriftMaster Global Holdings, Inc. and TM Global Biosciences, LLC.

[11] Nov. 16, 2022 warning letter to CBD American Shaman, LLC.

[12] Nov. 16, 2022 Warning Letter, Naturally Infused LLC, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/naturally-infused-llc-628036-11162022.

[13] 21 U.S.C. §§321(ff)(2), 350(c)(1)(B)(i)-(ii).

[14] Nov. 16, 2022 letter to CBD American Shaman, LLC, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/cbd-american-shaman-llc-628753-11162022.

[15] Nov. 16, 2022 letter to Newhere Inc dba CBDFX, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/newhere-inc-dba-cbdfx-629243-11162022; see also Nov. 22, 2019 warning letter to Bella Rose Labs, citing description of gummies as "fruity," "yummy," and "delicious," https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bella-rose-labs-594246-11222019.

[16] See 21 CFR section 117.5(e).

[17] FDA, "Overview of Food Ingredients, Additives & Colors," https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors#how.

[18] N.Y.C.R.R., title 9, sections 114.8(b), 114.9(b), and 114.9(f).

[19] See Cal. Health & Safety Code section 110469(a), 111925(a).