Navigating the Regulatory Structure for the Processing, Distribution and Selling of Cannabinoid Related Compounds, Including CBD

Part One: Regulatory

By Joe Reardon, Consumer Protection Assistant Commissioner NCDA&CS

I. Where we are now:

A. Hemp was reintroduced into the United States as a crop under agricultural pilot programs for purposes of research by the Agricultural Act of 2014 ("2014 U.S. Farm Bill"). Pub. L. 113-79.

B. The Agriculture Improvement Act of 2018 ("2018 U.S. Farm Bill), Pub. L. 115-334, decriminalized hemp and the production of hemp, and expanded the definition of hemp to include cannabinoid related compounds, including cannabidiol ("CBD").

1. Specifically, the 2018 U.S. Farm Bill excluded hemp from the definition of marijuana under the Controlled Substances Act, 21 § U.S.C. 802(16).

2. There is no legal definition difference between "hemp" and "industrial hemp." The 2014 U.S. Farm Bill refers to the plant as industrial hemp while the 2018 U.S. Farm Bill refers to the plant as just hemp.

3. The term hemp means 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 (THC) concentration of not more than 0.3 percent on a dry weight basis. 7 U.S.C. § 1639o(1).

C. While the 2018 U.S. Farm Bill decriminalized hemp, it did not affect existing U.S. Food and Drug Administration ("FDA") laws and regulations regarding the marketing of hemp products such as CBD as food, dietary supplements, or drugs. *See* 21 U.S.C. § 301 *et seq*. *See also United States v. Mallory*, No. CV 3:18-1289, 2019 WL 252530, at *3 (S.D. W. Va. Jan. 17, 2019) (cautioning the defendant in an order lifting a preliminary injunction that touting health benefits of CBD or adding it to food or health products without approval risks running afoul of the Federal Food, Drug, and Cosmetic Act).

1. It is still currently prohibited under the Federal Food, Drug, and Cosmetic Act ("FFD&CA") to introduce food containing added CBD into interstate commerce, or to market CBD products as, or in, dietary supplements. *See* Amy Abernethy and Lowell Schiller, *FDA is Committed to Sound, Science-based Policy on CBD*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd (last visited October 31, 2019).

2. FDA currently prohibits these uses because CBD was the subject of substantial clinical investigations into its potential medical uses before it was added to foods, including dietary supplements, and, separately, because CBD is the active ingredient in Epidiolex, an FDA-approved prescription drug product to treat rare, severe forms of epilepsy. *Id.*

3. The drug exclusion rule generally prohibits adding drugs to food. 21 U.S.C. § 331(ll).

4. One exception is if CBD was marketed as food or dietary supplement before any approval of it being a drug and before any substantial clinical investigations involving CBD were authorized. *See id.*

5. FDA has determined that, based on available evidence, this exception does not apply. *See FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers (last visited October 31, 2019).

II. Consumer protection concerns:

A. There has been a proliferation of CBD products, ranging from cosmetics, lotions, salves, tinctures, to both human and animal food added or infused with CBD, and CBD products claiming to have healing or health benefits.

1. In North Carolina, a recent survey conducted by the North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division, of the 1,564 different products surveyed from 101 stores, 59% are food products, 22% are dietary supplements, and 18% are floral material. 24 had made medical claims. *See* Appendix I.

2. There is no guarantee that CBD products contain the ingredients as advertised and there are no testing requirements. For example, CBS 58 Milwaukee went to stores in Milwaukee and Waukesha counties and purchased 20 different CBD items, including popcorn, gummies, and oils, and submitted them to two laboratories for analysis. Of the 20 products tested, only 4 had between 75% and 100% of the CBD listed on the package and 1 had about 50%. 8 tested products had less than 25% of the CBD it promised and 4 didn't contain any CBD. Kristen Barbaresi, *Shocking results: Do CBD products contain what they claim?*, CBS 58 WDJT – MILWAUKEE, https://www.cbs58.com/news/cbd-test-shocking-results (last visited October 31, 2019).[1] Additionally, warning letters issued by FDA in 2015 and 2016 shows that many products with CBD label claims were tested to have less than the advertised CBD, with some products testing negative for cannabinoids. *Warning Letters and Test Results for Cannabidiol-Related Products*, FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products (last visited October 31, 2019).

B. FDA has not yet announced any compliance strategy regarding CBD in food.

1. FDA is, however, taking action with regards to firms making health claims and has issued warning letters. *Warning Letters and Test Results for Cannabidiol-Related*

[1] The presenters have not verified the testing methods used by the laboratories and have not verified CBS 58 Milwaukee's sampling methods. This information is only provided as examples of the risks of purchasing unregulated CBD products.

Products, FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products (last visited October 31, 2019).

2. Warnings have been issued for selling unapproved CBD products that make unsubstantiated claims regarding treatment of cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety, among other conditions and diseases. *FDA warns company marketing unapproved cannabidiol products with unsubstantiated claims to treat cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer (last visited October 31, 2019).

C. The Federal Trade Commission ("FTC") has joined FDA in sending warning letters to companies advertising and selling products containing CBD claiming to treat Alzheimer's, cancer, and other diseases. *See FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, FEDERAL TRADE COMMISSION (April 2, 2019), https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companies-advertising (last visited October 31, 2019).

D. States have taken different approaches to firms adding CBD to food. For example:

1. The Colorado General Assembly has amended their food and drug act to state that products produced by registered wholesale food manufacturing facilities containing hemp, including naturally occurring cannabinoids, compounds, etc., are not adulterated or misbranded by virtue of it containing hemp. *See* 2018 Colo. Sess. Laws. 2032.

2. Texas recently enacted legislation that makes products containing CBD, intended for ingestion, considered as food and not controlled substances or adulterated solely on the basis that it is a consumable hemp product. *See* H.B. 1325, 86 Leg., Reg. Sess. (Tex. 2019).

3. The California Department of Public Health, Food and Drug Branch, has issued a statement indicating that introducing or delivering into interstate commerce any food added with CBD is prohibited. *FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products*, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (revised July 6, 2018), https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/HEMP/Web%20template%20for%20FSS%20Rounded%20-%20Final.pdf. However, there is pending legislating to make the inclusion of hemp or CBD not adulterated. *See* Assem. Bill No. 228, Reg. Sess. (Cal. 2019-2020).

4. New York City is embargoing food and drink products that contain CBD. *See* NYC DEPARTMENT OF HEALTH AND MENTAL HYGIENE, https://www1.nyc.gov/site/doh/business/food-operators.page (last visited October 31, 2019).

5. North Carolina has issued public notices regarding the legality of CBD. *See Regulators notify industry regarding CBD products in the marketplace*, NCDA&CS,

https://www.ncagr.gov/paffairs/release/2019/RegulatorsnotifyindustryregardingCBDproductsinthemarketplace.htm (last visited October 31, 2019).

6. Alaska has issued consumer alerts, warning about unregulated CBD and informing the public that these products are not FDA approved. Consumer Protection Unit Warns Consumers About Unregulated CBD Oil, ALASKA DEPARTMENT OF LAW http://www.law.alaska.gov/press/consumer_alerts/2018/1118-CBDoil.html (last visited October 31, 2019).

7. Other states are waiting on guidance from FDA.

E. The market is currently ahead of the regulatory environment.

III. Risks, mitigation strategy, and the next step:

A. The risks of not having regulations for CBD include a danger to public health and a loss of consumer confidence.

1. FDA held a public hearing on May 31, 2019 to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds.

2. Information presented at the public hearing suggests CBD may have unknown and adverse drug interactions. CBD have drug to drug interaction potential, specifically enzyme inhibition. CBD can cause drugs to have a stronger or weaker effect than intended.

3. Concerns raised with FDA include that CBD can cause liver injury at certain dosages, has potential for drug interactions, and can further exacerbate other agents that have hepatoxicity, such as Tylenol (acetaminophen).

4. Safe concentrations and daily intake levels have yet to be developed beyond the Epidiolex studies.

5. Additional studies should be done to understand the impact CBD may have on vulnerable populations, i.e., children, pregnant women, and patients over 55.

6. Many of the CBD products that are currently on the market are traditionally consumed by children, i.e. CBD gummy bears and candy (suckers).

B. There have been lawsuits brought by consumers related to CBD.

1. For example, in New York, a truck driver who tested positive on a drug test administered by his employer sued the manufacturer and distributer of the CBD oil he purchased, alleging, among other things, that defendant misrepresented the product did not contain THC. Defendant's CBD oil contained a detectible albeit small amount of THC but had represented on its website under an FAQ when discussing the difference between CBD from hemp and CBD from medical cannabis that "[w]hile the two plants are botanically related, our hemp contains no THC…."

The U.S. District Court, Western District of New York, allowed this claim to proceed while dismissing other claims and it is currently still pending. *See Horn v. Med. Marijuana, Inc.*, 383 F. Supp. 3d 114 (W.D.N.Y. April 17, 2019) (appeal filed).

2. This shows that misrepresentations of CBD products can and will be litigated.

C. How can the FDA, states, and industry lower the risks to the public, loss of consumer confidence in the market?

1. There are existing current good manufacturing practices (cGMPs), under FDA regulations, that can be adapted for hemp products, including CBD and CBD related compounds.

    i. 21 C.F.R. pt. 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

    ii. 21 C.F.R. pt. 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

    iii. 21 C.F.R. pt. 507 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

2. State regulatory agencies need to work with both FDA and industry to develop scientific approaches to protect public health and consumer confidence by considering ways to ensure:

    i. Identity;

    ii. Purity;

    iii. Strength; and

    iv. Composition.

D. 21 C.F.R. pt. 111 requires dietary supplements to consistently meet the established and written specifications for identity, purity, strength, and composition, and limits on contaminants, and requires dietary supplements to be manufactured, packaged, labeled, and held under conditions to prevent adulteration. *See* 21 C.F.R. § 111.3 (defining the term "quality") and 21 C.F.R. pt. 111, Subpart F ("Production and Process Control System: Requirements for Quality Control").

E. Under 21 C.F.R. pt. 111, a dietary supplement is required to be what it says it is, to have the identity, purity, strength, and composition it represents to have. Rather than scrutinizing just the finished product, the cGMP is designed to control the production process. *See United States v. Cole*, 84 F. Supp. 3d 1159, 1167 (D. Or. 2015). This cGMP can be adapted for hemp products, including CBD and CBD related compounds.

1. Manufacturers would be required to establish precise specifications for the identity, strength, purity, and composition of each component;

2. Test each incoming shipment of components to ensure it conforms to that specification;

3. For each product, detail each step of the manufacturing process in a formal Master Manufacturing Record document; and

4. Each time a batch is produced, keep a Batch Production Record.

F. A component of these FDA cGMPs include supplier verification, including at the growing stages of hemp. This provides accountability and traceability. *See, e.g.*, 21 C.F.R. pt. 117, Subpart G.

1. The supply chain verification program requires the receiving facility to establish and implement a risk-based supply-chain program for those raw materials and other ingredients. *Id.*

2. The receiving facility would verify suppliers through activities such as audits or sampling and testing of raw materials and other ingredients. *See* 21 C.F.R. §§ 117.410-117.415.

G. Proper record keeping for food safety may also help industry. For example:

1. On January 24, 2019, Big Sky Scientific LLC, while shipping thousands of pounds of hemp from a farm in Oregon to its processing facility in Colorado, had its shipment seized in Idaho, and its driver charged with marijuana trafficking.

2. The company argued that the 2018 U.S. Farm Bill, including protection of interstate shipment of hemp, preempted Idaho's marijuana laws. The company produced a copy of the farmer's "industrial hemp license" and reports from two different laboratories to show that seized product was in fact hemp and not marijuana.

3. Due to the perishable nature of the crop, Big Sky Scientific LLC filed for an emergency motion for temporary restraining order and preliminary injunction for the return of the crop or for a receiver to properly store the crop. The U.S. District Court, District of Idaho, denied the motion and the injunction because, in part, there was an issue as to whether the product seized was "hemp." *See Big Sky Sci. LLC v. Idaho State Police*, No. 1:19-CV-00040-REB, 2019 WL 438336, at *6 (D. Idaho Feb. 2, 2019) and *Big Sky Sci. LLC v. Idaho State Police*, No. 1:19-CV-00040-REB, 2019 WL 2613882, at *15 (D. Idaho Feb. 19, 2019).

i. The court in the order denying the emergency motion questioned the value of the company's evidence, including the laboratory reports, pointing out one of the reports had blanks where there should be listings of batch number, batch size, and harvest/production date.

ii. By following the standards set forth under 21 C.F.R. pt. 111, supply chain verification, and the other FDA regulations, industry may have more evidence readily available to show the source of any detained shipment of hemp.

iii. The denial of the preliminary injunction is currently before the 9th Circuit Court of Appeals, and Big Sky Scientific LLC argues, *inter alia*, that because the hemp was produced under a 2014 U.S. Farm Bill pilot program that it is protected by the 2018 U.S. Farm Bill interstate transport provision. This position is supported by the United States Department of Agriculture. *See* Brief of Appellant Big Sky Scientific LLC, Case No. 19-35138 (9th Cir. 2019), https://cdn2.hubspot.net/hubfs/5733031/BigSky_May2019/Doc/PDF/Big-Sky-Opening-9th-Cir.-Brief.pdf and *Executive Summary of New Hemp Authorities*, USDA (May 28, 2019) https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf.

IV. Conclusion

A. The cGMPs would apply the same standards currently followed by firms that manufacture, process, package, label, and hold food, both human and animal, and dietary supplement.

B. This adaptation can come from FDA or by states. States can adapt these cGMPs for hemp products through legislation or, if existing rulemaking authority exist, do so through agency rulemaking.

Part Two: Industry

By Scott Propheter, Vice President of Agronomy and Outreach, Criticality, LLC

I. Background of Criticality

A. Criticality is an experienced and entrepreneurial combination of agricultural expertise and international bioproduct processing technology focusing on industrial hemp processing and value-added agricultural products. Formed in 2016 as a partnership with Thar Process. 2017 formed a partnership with Pyxus International, a global agricultural production company.

B. Began pilot scale operations in Hobgood, NC in 2017. Criticality conducted a year of process/protocol development before releasing products.

C. In March of 2019, Criticality opened a 55,000 square foot facility in Wilson, NC. This facility was designed and retrofitted to comply with good manufacturing practices and dietary supplement standards.

II. Navigating the regulatory grey area

A. Due to the lack of regulation since the forming of the company, every decision that is made must anticipate future regulation.

B. North Carolina initially lacked the necessary legislative framework to regulate processors of industrial hemp.

C. Testing standards for industrial hemp and CBD products have been lacking, and vary greatly from State to State. Criticality has established its own testing standards based on several

established State cannabis programs[iii], in conjunction with regulators, and through its own research to ensure all products are safe for consumers.

III. Challenges ahead

A. The industrial hemp industry is currently in its infancy. New challenges in the regulatory environment emerge on an almost daily basis.

B. Methods and standards for the quantification of cannabinoids are commercially available, but vary from supplier to supplier. This can lead to confusion between industry and regulators surrounding the concentration of cannabinoids and labeling in CBD products.

C. Current industry testing standards for contaminants include heavy metals, pesticides, and micro biologicals[iii]. Future contaminant issues can and will arise, and must be considered by industry and regulators before they become an issue.

D. Most participants in the industry will take the path of least regulatory resistance, and will comply with only what is established and codified. Working hand in hand with the regulatory bodies, leaders in this industry must set a higher standard and anticipate future issues to gain a competitive advantage and ensure their longevity.

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[i] https://www.bcc.ca.gov/law_regs/cdph_prop_text_emerg_reg.pdf
[ii] https://www.mass.gov/files/documents/2018/03/27/935cmr500.pdf
[iii] http://www.proverdelabs.com/Services-Home/cbd

Appendix I

North Carolina

101 Stores

Category	# Surveyed	# Stores with Category	% Stores with Category
Total Products	1564		
Food Products	927 (59% of total)	86	**85%**
Dietary Supplement	350 (22% of total)	54	**53%**
Floral Material	287 (18% of total)	73	**72%**
Medical Claims	24	15	**15%**

Distribution of Products:

Category	Type	#	% Type per Category	% Type per Total Products
Food Products	candy	507	55%	32%
	food	252	27%	16%
	beverage	168	18%	11%
Dietary Supplement	candy	22	6%	1%
	other	328	94%	21%
Floral Material	Flower	145	51%	9%
	Rolled	83	29%	5%
	Vape	27	9%	2%
	other	32	11%	2%