

CBD: A Year in Review

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Agenda

- Plant Background
- The 2018 Farm Bill
- CBD in Food, Dietary Supplements, and Cosmetics
- CBD Enforcement and Litigation
- Proposition 65
- COVID-19 and CBD
- Industry Takeaways
- Questions

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Plant Background: Marijuana vs. Hemp

- *Cannabis sativa L.*: A plant species that is part of a genus of flowering plants called “Cannabis”
 - Varieties include **both** marijuana and hemp
- Marijuana
 - Contains over 0.3% THC
 - Considered a Schedule I controlled substance under federal law
- Hemp
 - Cannabis plant *not* used as a drug
 - Generally, grown for use in food, dietary supplements, fabrics, textiles, etc.

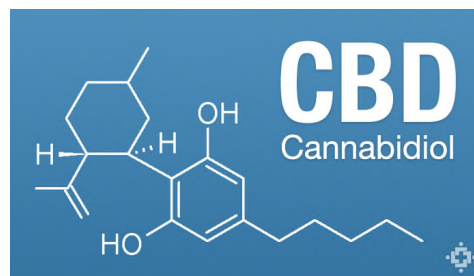


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Plant Background: What Is CBD?

- One of many cannabinoids found in the Cannabis sativa plant
- Non-mind-altering compound
- Contains negligible amounts of THC



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Plant Background: Terpenes

- Class of organic compounds produced by many plants
- More than 100 in cannabis plants
- Responsible for aroma & taste
- Synergy of cannabinoids and terpenes



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Plant Background: Who Regulates CBD?

	FDA	FTC	DEA	USDA
Legal Authorities	<u>Federal Food, Drug & Cosmetic Act (FDCA)</u> Misbranding Adulteration	<u>Federal Trade Commission Act</u> False and Misleading Advertising Deceptive Marketing Practices	<u>Controlled Substances Act</u>	<u>2018 Farm Bill</u>
Issues	Label Format and Content Claims & Intended Use Manufacturing & Quality Assurance Ingredients / Product Safety	Express and Implied Claims Substantiation Endorsements & Testimonials Online Marketing (Payment terms, privacy disclosures, data security, etc.)	Manufacturing, Distribution, and Advertising of Controlled Substances	Growth, Cultivation, and Licensure of Hemp*
Investigative Tools	Inspections / 483s Warning Letters Import Detention	Civil Investigative Demands	Inspections, Warning Letters, and Investigations	Inspections and Crop Testing*
Enforcement	Product Seizures Injunctions Civil/Criminal Penalties	Asset Freezes Temporary Restraining Orders / Injunctions Civil Litigation	Criminal/Civil Penalties	Varies at State Level*

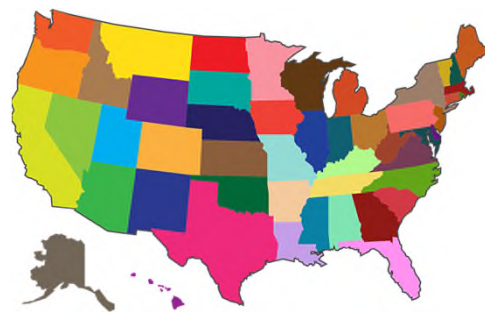
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*USDA reviews and approves hemp programs; states set own rules on hemp crop testing.

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Plant Background: Who Regulates CBD?

- Various State-Level Agencies
 - State Attorneys General
 - State Departments of Agriculture
 - State Departments of Health
 - State Boards of Pharmacy
- State-to-state differences on regulations, licensure processes, testing requirements, etc.



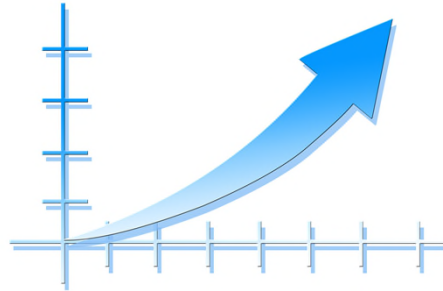
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Plant Background: What Makes CBD Important?

Three Competing Forces

- Increasing consumer interest in CBD products and CBD-related therapies
- Wide-ranging and lucrative industry for CBD and CBD-containing products (e.g., cosmetics, edibles, etc.)
- Continuing legal uncertainties at the state and federal levels about using CBD in consumer products



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2018 Farm Bill

Pre-Farm Bill

- All cannabis plants, whether marijuana or hemp, were considered Schedule I controlled substances under federal law
- Any cannabis plant derivatives, including CBD, were *per se* unlawful and subject to criminal penalties
- Very narrow exception carved out for products derived from specific parts of the plant (mature stalks, non-resin seeds)



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2018 Farm Bill: What It Did

- Agriculture Improvement Act of 2018 (the “2018 Farm Bill”)
 - **Signed into law December 20, 2018**
 - Removed hemp and all its derivatives from the federal definition of marijuana; defined as any cannabis plant with no more than 0.3% THC
 - Established USDA as the regulator for hemp as an agricultural commodity



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2018 Farm Bill: Industrial Hemp Programs

- Under the 2018 Farm Bill, states are allowed to seek USDA approval for hemp cultivation and research programs
 - States can allow cultivation, domestic import/export, and processing of hemp
 - States may opt to take part in a USDA-run industrial hemp program
 - All hemp must not exceed 0.3% THC by weight



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Example: Industrial Hemp Regulations

Illinois Department of Agriculture, Notice of Adopted Rules –
Industrial Hemp Act

Section 1200.20 General Provisions

- a) No person shall cultivate industrial hemp in the State without first receiving an Industrial Hemp Cultivation License from the Department.
- b) No person shall process or handle industrial hemp in the State without first receiving a processor/handler registration from the Department.
- c) All licensees in the State must provide reports as outlined in Section 1200.40(a) and (b).
- d) Licensed industrial hemp cultivators are solely responsible for procuring seeds, clones, transplants or propagules for planting.

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Section 1200.100 Other Prohibited Activities

- a) A licensed person shall not plant or grow hemp on any site not listed in the application.
- b) A licensed person shall not ship or transport, or allow to be shipped or transported, live hemp plants, cuttings for planting, or viable seeds from a variety that is currently designated by the Department as a prohibited variety or a variety of concern to any location outside the State of Illinois.
- c) A licensed person shall not ship or transport, or allow to be shipped or transported, any hemp product with a delta-9 THC concentration in excess of 0.3%.

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Key Takeaways

- The Farm Bill **did**:
 - Remove “hemp” as a controlled substance
 - Establish a pathway for USDA and state-regulated “hemp production”
 - Repeal of “industrial hemp research” provision at 7 U.S.C. § 5940 one year after Dept. of Ag. Regulatory scheme is established
- The Farm Bill **did not**:
 - Legalize marijuana or marijuana-derived CBD
 - Change FDA’s authority over cannabis derivatives
 - Preempt state laws prohibiting Industrial Hemp

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FDA-Regulated: Food

- FDA has **not** changed its position that CBD (including hemp-derived) may **not** be sold as or in a food
- In foods, CBD is not considered by FDA as an approved food additive or “generally recognized as safe” (GRAS)



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FDA-Regulated: Dietary Supplements

- Similarly, CBD (whether derived from marijuana or hemp) is not considered a lawful dietary ingredient by FDA
- Section 201(ff) of FD&C Act (21 U.S.C. § 321 (ff)(3)(B): Definition of Dietary Supplement does not include “an article”:
 - Approved as a new drug, antibiotic, or licensed biologic; or
 - Authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public; and
 - which was not before such approval or investigation....marketed as a dietary supplement or as a food....”
- Therefore, even if an article was clinically investigated, if it was marketed as a food or a dietary supplement prior to those investigations it still meets the definition of a dietary supplement.

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FDA-Regulated: Cosmetics

- Cosmetics are not subject to the same regulatory hurdles restricting food and dietary supplements
- Overarching safety hook over cosmetics
- Drug claims are a primary concern
- FDA has initiated a research study in partnership with the University of Mississippi to assess sensitization of THC and CBD topically, and dermal penetration



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Practical Concerns

- FDA has taken a hard stance on the use of CBD in **any** ingestible product
- FDA enforcement risk:
 - Priority is on egregious product claims and targeting vulnerable populations (e.g., the elderly, chronically ill patients)
- Follow-on lawsuits and state enforcement actions are likely



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FDA Developments

- Recognizing that the 2018 Farm Bill paved the way for CBD use in consumer products, FDA is currently evaluating a range of CBD issues
- 2019
 - May 31, 2019 hearing: FDA discussed safety risks of CBD use (e.g., cumulative exposure, adverse events, drug interactions, use by vulnerable populations), unclear industry definitions for CBD, and issues relating to CBD production and quality
 - Various public statements from FDA reflecting hesitancy about CBD safety, risks of liver injury, and male reproductive toxicity

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Recent Developments

■ 2020

- FDA issued a press release and congressional report on its current CBD stance
- Largely echoes concerns raised in 2019; FDA is still aware of the large consumer interest in CBD, but is concerned about public perceptions that all CBD products on the market are safe
- FDA identified a series of CBD “knowledge gaps” (e.g., effects of sustained use, purity of CBD in the marketplace, CBD absorption pathways)
- Reopened its docket to collect CBD information indefinitely
- Indicated an enforcement policy may be forthcoming
- Seeking information to distinguish “broad”/ “full” spectrum & isolates

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FDA Request for Information

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. The risk of liver injury from CBD; 2. Toxicities of some of the active metabolites of CBD; 3. Impact of CBD on the male reproductive system; 4. Effect of CBD co-administration; 5. Impact on neurological development; 6. Sedative effects of CBD; 7. Transdermal penetration and pharmacokinetics of CBD; 8. Effect of CBD on pets and food-producing animals; | <ol style="list-style-type: none"> 1. Clinical studies (including real world data/evidence) to address safety questions related to long-term sustained or cumulative exposure to CBD, including in vulnerable populations such as children, the elderly, and women who are pregnant or breastfeeding; 2. Long-term (chronic) repeated dose toxicity studies in appropriate animal models, evaluating the most relevant toxicological end points; 3. Clinical studies on the effect of different routes of CBD administration on its safety profile; 4. Studies to characterize the potential for bioaccumulation of CBD over long-term exposure; and 5. Effect of CBD on the eye. |
|--|--|

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FDA Enforcement

Warning Letters

- In 2019, 22 letters sent – 15 in November alone
- Focus on “egregious claims”
 - CBD as a treatment or cure for disease or chronic illness
 - Pain
 - Diabetes
 - Cancer
 - Opioid addiction
 - Schizophrenia



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WARNING LETTER

KOI CBD LLC

MARCS-CMS 593391 – NOVEMBER 22, 2019

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at <https://koicbd.com> in September 2019 and has determined that you take orders there for the products “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” “KOI CBD Infused Shot” (three varieties), “KOI Naturals CBD Spray for Pets,” and “KOI CBD Soft Chews,” all of which you promote as products containing cannabidiol (CBD). The claims on your website establish that your “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” and “KOI CBD Infused Shot” 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, your 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 “KOI Naturals CBD Spray for Pets” and “KOI CBD Soft Chews” products are unapproved new animal drugs that 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).

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Unapproved New Drugs

Based on our review of your website, your “CBD HEALING BALM,” “CBD VAPE OIL,” “FULL SPECTRUM CBD TINCTURE,” “KOI LOTION,” “KOI CBD Gummies,” and “KOI CBD Infused Shot” 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://koicbd.com>, that establish the intended use of your products as drugs include, but may not be limited to, the following:

On your webpage titled “8 Proven Benefits of CBD”:

- “CBD RELIEVES PAIN AND INFLAMMATION”
- “studies show that CBD prevents human experimental psychosis and is effective in open case reports and clinical trials in patients with schizophrenia, with a remarkable safety profile.”
- “Not only does the research show that CBD benefits including being effective in fighting breast cancer cells, data also suggest that it can be used to inhibit the invasion of lung and colon cancer, plus it possesses anti-tumor properties in gliomas and has been used to treat leukemia.”
- “CBD LOWERS INCIDENCE OF DIABETES”

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FTC Enforcement

- Primary jurisdiction over **advertising**
 - Most interested in what may influence consumer purchasing decisions
 - Concurrent regulation with FDA on health-related CBD claims
- When evaluating claims, FTC’s interest is **proper substantiation**
 - “Competent and Reliable Scientific Evidence” (CRSE)
- Not limited to product labels
 - Social media (posts, “likes,” consumer reviews)
 - Influencers & material connections



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Example: FTC Letter to 4Bush Holdings, LLC

September 9, 2019

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The Federal Trade Commission ("FTC") is an independent federal agency whose mission is to maintain a competitive marketplace for the benefit of both businesses and consumers. The FTC seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices, and by educating consumers and businesses about their rights and responsibilities. We are writing to express concern that you may be making false or unsubstantiated advertising claims about the health benefits of products containing cannabidiol (CBD), a chemical compound derived from the cannabis plant.

Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, prohibit unfair or deceptive advertising. Specifically, it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the advertiser possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made. This substantiation requirement applies whether the advertiser disseminates such health claims directly via traditional advertising or indirectly via the use of a product name, website name, or metatags. This requirement also extends to consumer endorsements. It's not enough that an endorsement represents the consumer's honest opinion or experience. Reasonable consumers may interpret an endorsement claiming a health benefit from the use of a product as representing that the product is likely to be effective in achieving that benefit. Under FTC law, an advertiser must possess and rely on competent and reliable scientific evidence to support health claims, both express and implied, made through the use of endorsements.

We strongly urge you to review all claims for your products, including consumer testimonials, and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a federal district court injunction or an administrative cease and desist order. An order also may require that you refund money to consumers.

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The Science of CBD (CANNABIDOIL)

CBD Oil has been medically proven to positively regulate your endocannabinoid system] addressing issues such as... hypertension[] and even cardiovascular issues....

- **Psychological Benefits:** [I]n some cases may offer a safe remedy for depression and bipolar disorders.
- **Neurological Benefits:** Our CBD Oil's positive impact on the neural system helps reduce age-related cognitive decline....

CBD has now been clinically proven to:

Reduce social anxiety, cognitive impairment, and discomfort in patients diagnosed with Generalized Social Anxiety Disorder (SAD)
 Decrease cancer spread by "turning off" genes involved in tumor development
 Combat neurodegenerative disorders like Alzheimer's by removing plaque that block neuron-signaling
 Reduces cigarette addiction by modulating the rewarding effects of nicotine
 [R]estore respiratory stability to those experiencing sleep Apnea
 Clears acne by inhibiting lipid synthesis on the skin
 Regulates blood sugar and lowers insulin resistance
 Provide relief to those suffering from IBD (Chron's [sic] or Colitis) through its anti-inflammatory effects
 Improves symptoms of MS (multiple sclerosis) by providing durable protection to neurons
 Prevents obesity....

[Dr. Jamie Richardson] teamed up with his group of Harvard researchers to create Complete Relief CBD, a brand of medical grade CBD supplements developed through thousands of hours of research and clinical trials....

SPECIAL REPORT: Woman Paralyzed By Pain Discovers Breakthrough Relief Called 'Nature's Oxycontin'....

Complete Relief CBD has been called "Nature's Oxycontin" because it **quickly relieves even the most agonizing pain.... Many say it works like magic.** Some say it works better than prescription painkillers like Vicodin and Oxycontin....

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Private Litigants

- Various bases for challenges
 - "Baby" FDA/FTC Acts
 - Consumer Protection Laws
- McCarthy v. Elixinol LLC (N.D. Cal., Dec. 4, 2019)
 - Class action complaint regarding use of CBD as an unapproved dietary supplement
- Ahumada v. Global Widget LLC (D. Mass., Sept. 24, 2019)
 - Class action complaint regarding mislabeling of CBD content



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Proposition 65 Updates

Safe Drinking Water and Toxic Enforcement Act of 1986 ("Prop 65")

- Governor publishes a list of chemicals known to cause cancer, birth defects, or other reproductive harm
- Businesses required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical
- Breeding ground for AG enforcement and private class actions in California



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Proposition 65 Updates

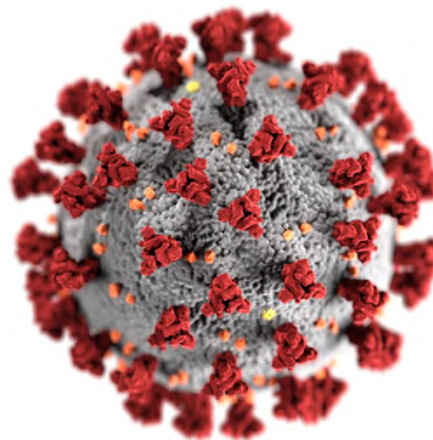
- THC has been added to the Prop 65 chemicals list
- **All products containing any THC will require a Prop 65 warning for reproductive toxicity as of January 3, 2021**
- There is no safe-harbor level – any amount of THC will trigger a warning if sold in California
- Failure to comply with Proposition 65 warning requirements can result in statutory violations of \$2,500 per violation per day

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COVID-19 and CBD

- The ongoing COVID-19 pandemic has led to a spike in companies advertising and selling purported tests, cures, and treatments for COVID-19
- FDA and FTC have issued 27 joint warning letters to date
- Four letters implicate CBD
 - CBD Online Store
 - Native Roots Hemp
 - Indigo Naturals
 - Neuro XPF



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WARNING LETTER

Indigo Naturals

MARCS-CMS 606423 – APRIL 06, 2020

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address <https://indigonaturals.net> on March 30, 2020 and April 2, 2020, respectively. We also reviewed your social media website at Internet address www.facebook.com/IndigoNaturals/, where you direct consumers to your website, <https://indigonaturals.net>, to purchase your products. The FDA has observed that your website offers cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19^[1] in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

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Some examples of the claims on your websites that establish the intended use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “Is CBD An Anti-Viral Agent For Coronavirus, Influenza, MERS, and SARS . . . CBD Anti VIRAL? . . . The headlines are frightening from Wuhan, China when we first wrote this. . . What about CBD? We’ve seen reports of CBD having both antibacterial and antiviral effects. . . Can CBD Help with Viruses Like Coronavirus And Influenza . . . CBD’s real benefit may be on the high-end immune response as we saw with MS: Moreover, CBD administration at the time of viral infection exerts long-lasting effects, ameliorating motor deficits in the chronic phase of the disease in conjunction with reduced microglial activation and pro-inflammatory cytokine production. . . CBD will boost two of the T-cells powerful weapons (interferon and IL2) WHEN T cell function is LACKING. When T cell activity is too strong, it will actually suppress that activity . . . Levels of T cells in the lungs are important for the new coronaviruses” [from a February 12, 2020 blog posting on your website <https://indigonaturals.net>]
- “Updated information on CBD (ACD2 receptors) and anti-viral effects in age of coronavirus: <https://indigonaturals.net/.../is-cbd-an-antiviral-agent-for> . . . Is CBD an Anti-Viral Agent for Coronavirus, Influenza, MERS, and Sars [sic] Plus Key Antiviral Supplements?” and the image of viruses with the words “CBD Anti VIRAL?” [from a February 26 post on your social media website <https://www.facebook.com/IndigoNaturals/>]

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Industry Takeaways

- CBD industry is growing at a breakneck pace in the U.S., but poses many regulatory issues for stakeholders at the state and federal levels
- CBD products should not make unlawful disease claims
 - Claims purporting to treat or cure disease (including COVID-19) are especially risky, and are an enforcement priority for FDA
- Ingestible CBD products are still considered *per se* unlawful
- Do not neglect state laws; these are still an evolving patchwork
- CBD research is being sought by FDA
 - The CBD industry should take an active role in helping FDA develop the best possible scientific bases for issuing new regulations

Questions?



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