A YEAR IN CANNABIDIOL (CBD):

Measured progress and path forward

Since the U.S. Food and Drug Administration (FDA) held its Public Hearing on "Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds" on May 31, 2019, substantial efforts have been made to address poor quality, fraudulent or otherwise dangerous CBD-containing products on the market. In response to the COVID-19 pandemic, state, federal and international regulators and enforcement bodies continue to address consumer health and safety threats – including targeting fraudulent CBD-containing products marketed to mitigate, prevent, treat, diagnose or cure COVID-19.

Coupled with increased efforts to educate consumers and to incentivize further CBD research and data development aligned with FDA's needs, opportunities exist to create a regulatory structure that promotes the availability of safe and quality CBD-containing products and gives industry and consumers alike a stable, predictable and safe CBD marketplace.

FEDERAL ACTIONS

FDA Indefinitely Reopens the CBD Public Docket to Collect Data Needed to Address Research Gaps and Uncertainties

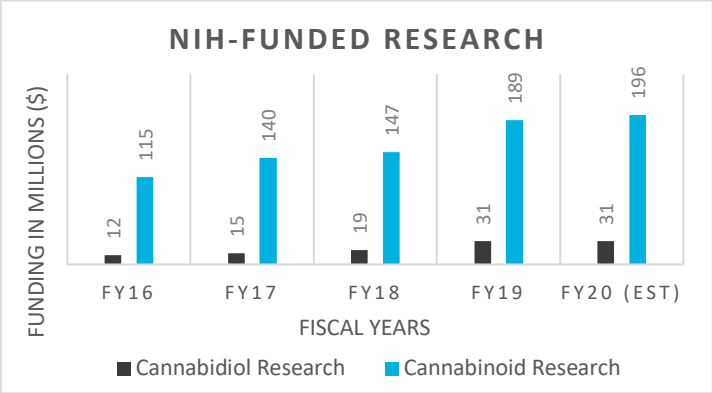
- On March 11, 2020, FDA reopened the public docket that accompanied the May 2019 hearing to provide a public and transparent way for stakeholders to provide new and emerging information regarding CBD in real time as it becomes available while protecting confidential data that should be accessible by FDA.
- The areas noted that would be most useful to inform FDA on the safety of CBD to further address data gaps and include opportunities to advance clinical data and systematic surveillance:[i]
  - Clinical Studies: These include studies regarding safety and tolerability, driving impairment, alcohol interaction, and dermal penetration.
  - Systematic Surveillance: The broad availability of CBD provides an opportunity to establish safety surveillance systems that could capture data about exposure and outcomes related to CBD uses that are not feasible or practical to generate using traditional clinical trials or studies.

FDA Warning Letters

Warning Letters Issued Since May 2019 **January 2015 – May 2019:** 20 total warning letters | **May 2019 – Present:** 30 total warning letters[ii]		
Joint FDA/FTC Warning Letters (21)	***COVID-19/CBD Specific Warning Letters (8)***	***FTC Specific Warning Letters (3)***
July 22, 2019: • Curaleaf, Inc.	March 31, 2020: • NeuroXPF	September 10, 2019: [iii] • 4Bush Holdings, LLC • NuLife CBD Oils, LLC • Ocanna Co.
September 12, 2019: • Herbal Healer Academy, Inc.	April 6, 2020: • Native Roots Hemp • Indigo Naturals	
September 18, 2019: • Alternative Laboratories	April 7, 2020: • CBD Online Store	
October 10, 2019: • Rooted Apothecary, LLC	April 16, 2020: • Nova Botanix LTD DBA CanaBD	***FDA Warning Letters (1)***
November 22, 2019: • Natural Native LLC • Private I Salon, LLC • CDRL Nutritional, Inc • Red Pill Medical Inc • Apex Hemp Oil LLC • Daddy Burt Hemp Co • Organix Industries, Inc dba Plant Organix • Sabai Ventures Ltd • Noli Oil, LLC • Bella Rose Labs • Sunflora, Inc./The CBD Store, LLC dba Your CBD Store • Infinite Product Company LLLP DBA Infinite CBD • Mr. Pink Collections, LLC • Whole Leaf Organics, LLC • KOI CBD LLC	April 20, 2020: • Homero Corp DBA Natures CBD Oil Distribution	April 28, 2020: • The Dragontree Apothecary LLC
	May 7, 2020: • AgroTerra, Ltd. dba Patriot Hemp Company	
	May 15, 2020: • Noetic Nutraceuticals	
	May 21, 2020: • Apollo Holdings, LLC	
	May 26, 2020: • CBD Gaze	

Overview of NIH-funded research for CBD-containing products.

NIH funding for research for both cannabidiol and cannabinoids has generally increased annually since 2016: [iv]



Year	CBD Research	Marijuana Research
FY16	$12 million	$115 million
FY17	$15 million	$140 million
FY18	$19 million	$147 million
FY19	$31 million	$189 million
FY20 (est)	$31 million	$196 million

Federal Enforcement Action

- In response to a Federal Trade Commission complaint, a California-based marketer of a dietary supplement has agreed to a preliminary order barring it from claiming that it is effective at treating, preventing, or reducing the risk of COVID-19. Pending the resolution of a parallel administrative case, the proposed preliminary order also bars the company, doing business as Whole Leaf Organics, from claiming that three CBD-based products he sells are effective cancer treatments.[v]

FDA ACTION NEEDED TO PREVENT FURTHER PATCHWORK OF STATE CBD REGULATIONS ON USE AND SALES

Examples of CBD-Specific State Legislation

While some states have passed a patchwork of inconsistent laws governing the use of CBD, others have engaged in enforcement actions against CBD manufacturers. Such activity has created widespread confusion as to the legality of the products and highlighted the need for one clear regulatory pathway.

State	Bill Number	Date Enacted	Purpose/Scope
Florida	SB 1020[vi]	Signed June 25, 2019. Enacted on July 1, 2019.	• Authorizes the distribution and retail sale of hemp extract. • Before hemp extract may be distributed or sold, it must be analyzed and certified by an independent testing laboratory to confirm the THC concentration does not exceed 0.3 percent on a dry-weight basis. • The bill also provides package labeling requirements for hemp extract products.
Oklahoma	SB 238[vii]	Signed May 13, 2019. Enacted November 1, 2019.	• SB 238 requires any product containing cannabidiol to contain a label showing the country of origin and whether the cannabidiol is synthetic or natural. • Doesn't apply to any FDA-approved pharmaceutical product. • Allows those selling hemp and hemp products to sell such products and add such products to other goods without a license.
Virginia	SB918[viii]	Signed April 6, 2020.	• Defines hemp extracts as food products for human consumption, failing under the Dept. of Agriculture and Consumer Services.

State enforcement actions regarding unauthorized sale of CBD-containing products.

- **On July 17, 2019, a coalition of 37 bipartisan Attorneys General** urged federal cooperation with the states to protect consumers from false advertising and potential harms to their health from products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD).[ix]
- **New York (April 6, 2020):** The office of the New York Attorney General sent a cease and desist letter[x] to CBD company Finest Herbalist for marketing through emails, text messages, and websites that consumers could use its products to "[f]ight back against the coronavirus outbreak," among other claims.
- **Oregon (April 28, 2020):** The Oregon Attorney General's Office warned a store in Portland that advertising that CBD products could boost immunity against the coronavirus was likely a violation of consumer protection laws.[xi]

U.S. ON PACE WITH OTHER INTERNATIONAL REGULATORY AGENCIES

While the US struggles with how to best address CBD, governments and regulators across the globe have been facing similar challenges. While governments have been moving forward at different paces, the US has kept on pace with most of our international counterparts.

	Australia	UK	Sweden	US
Court Action		CBD products with >1mg THC per container illegal.	• Supreme Court has ruled that CBD products are illegal if they contain any amount of THC • Without a prescription, it is illegal to possess CBD (or any form of cannabis)	Spike in CBD class actions suit, with 18 new suits filed since the May 2019 public meeting. Suits based on potential harms to class members caused by, among other things, manufacturers marketing their products with unsubstantiated health claims and mislabeling the CBD and THC content in their products.
Legislative Action				CBD and other cannabinoid products containing ≤0.3% THC are not controlled substances
Regulatory Action	• CBD currently listed in National Poisons Standard as Schedule 4 – Prescription Only Medicine • May 2020 publication of "Safety Review on the Safety of Low Dose Cannabidiol" • Proposal to shift CBD to Schedule 3 - Pharmacist Only Medicine - but subject to safety, quality and efficacy assessment and regulator approval. • Pharmacist consultation required, with Product Information supplied, before allowing purchase.	• Food Standards Agency (FSA) published consumer guidance and risk assessment for cannabidiol in February 2020 • No new products allowed on the market • FSA issued a March 2021 deadline for companies to submit and have validated a European Union novel food application; post deadline, unauthorized products removed from shelves • Medium-term – only authorized novel foods to be sold with requisite safety and quality data	The Swedish Medical Products Agency (MPA) position is that all CBD oils for oral consumption are medical products and therefore require approval from the MPA before being allowed to be sold.	FDA announces: • CBD cannot lawfully be added to foods and dietary supplements • CBD is not currently Generally Recognized as Safe • to reopen /"extend indefinitely" comment period given persistent dearth of existing scientific data and information on cannabis or cannabis-derived compounds If FDA eventually permits, CBD wouldbe a New Dietary Ingredient subject to pre-market notification of a reasonable expectation of safety
Dosing	• Proposed maximum < 60mg/ for adults aged 18 and over. • Pharmacist consultation would be required, with Product Information supplied, before allowing purchase.	Proposed maximum < 70 mg/day for healthy adults and advice to consult doctor before using CBD products		

[i] https://www.fda.gov/news-events/public-health-focus/information-cbd-data-collection-and-submission
[ii] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
[iii] https://www.ftc.gov/system/files/documents/foia_requests/foia-2019-01289_warning_letters_sent_to_cbd_companies_9-30-19.pdf
[iv] https://report.nih.gov/categorical_spending.aspx
[v] https://www.ftc.gov/news-events/press-releases/2020/04/thrive-supplement-marketer-agrees-preliminary-order-barring-him?utm_source=slider
[vi] https://www.flsenate.gov/Committees/billsummaries/2019/html/2027
[vii] http://webserver1.lsb.state.ok.us/cf_pdf/2019-20%20ENR/SB/SB238%20ENR.PDF
[viii] https://www.usnews.com/news/best-states/virginia/articles/2020-04-16/northam-signs-bill-to-regulate-cbd-products-as-food
[ix] https://oag.dc.gov/release/ag-racine-leads-37-attorneys-general-urging-fda
[x] https://ag.ny.gov/sites/default/files/letter_from_ny_attorney_general_to_finest_herbalist.pdf
[xi] https://www.doj.state.or.us/media-home/news-media-releases/oregon-department-of-justice-warns-against-making-coronavirus-cure-claims/