



Developments in Enforcement of CBD and Cannabis Products

Frederick (Rick) Ball, Partner, Duane Morris LLP and Treasurer,
FDLI Board of Directors

Richard Cleland, Assistant Director, Bureau of Consumer
Protection, Division of Advertising Practices, FTC

Aaron Negangard, Chief Deputy Attorney General, Indiana

Moderated by **Libby Baney**, Partner, Faegre Baker Daniels LLP



Developments in Enforcement of CBD and Cannabis Products

Richard Cleland

Assistant Director, Division of Advertising Practices

Federal Trade Commission

December 12, 2019



My comments reflect my own views and not necessarily those of the Commission or any individual Commissioner.

FDA/FTC Jurisdiction

- FDA and FTC have concurrent jurisdiction but different focuses when it comes to CBD.
- FDA has primary jurisdiction over the labeling of OTC drugs, food, dietary supplements, and cosmetics. Based on FDA warning letters, FDA's focus is on whether marketers are making unapproved drug claims and whether the product can be lawfully sold as a dietary supplement or an ingredient in food.
- FTC has primary jurisdiction over the advertising of OTC drugs, food, dietary supplements, and cosmetics. The FTC's primary focus is on false and unsubstantiated advertising claims.

See Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18, 539 (Sept. 16, 1971).

False and Deceptive Advertising

- Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in commerce.
- Section 12 of the FTC Act prohibits the false advertisement of food, drugs, cosmetics, devices, and services.

False and Deceptive Advertising

- False statements
 - CBD is clinically proven to cure Alzheimer's
- Unsubstantiated statements
 - CBD eliminates pain associated with arthritis
- Failure to disclose material facts
 - Safety claims
 - Contradictions (St. John's Wort)

Substantiation

- Advertisers must have a reasonable basis to support objective performance claims before those claims are disseminated.
- Claims that CBD provides a health benefit must be supported by competent and reliable scientific evidence.

Disease Claims

- Disease treatment claims will normally require one or more human clinical trials. *See, e.g., Thompson Med. Co.*, 104 F.T.C. 648, 821 (1984); *FTC v. Nat'l Urological Grp.*, 2017 WL 6759868, at *29 (N.D. Ga. 2017), *aff'd*, 2019 WL 4463503 (11th Cir. 2019); *POM Wonderful, LLC*, 2013 FTC LEXIS 6, at *67-68, 109 (Jan. 10, 2013), *aff'd*, 777 F.3d 478 (D.C. Cir. 2015); *FTC v. Wellness Support Network, Inc.*, 2014 U.S. Dist. LEXIS 21449, *52-53 (N.D. Cal. 2014); *FTC v. Health Research Labs., LLC*, No. 2:17-cv-00467 (D. Me. Jan. 16, 2018) (stipulated judgment); *FTC v. Nobetes Corp.*, No. 2:18-cv-10068 (C.D. Cal. Dec. 13, 2018) (stipulated judgment).

Human Clinical Trials: Disease Claims

- Conducted by qualified experts
- Appropriate design for the outcomes being investigated
- Control group
- Randomized
- Double-blinded
- Valid statistical analysis
- On the product or essentially equivalent product
- Representative population
- The length of the study must be sufficient to show claimed benefit
- Adequate study size
- Outcome variables match the claims
- Outcome measurements must be valid and reliable
- Compare treatment and control groups
- Results must be clinically significant
- Sufficient data is available for evaluation

Joint FTC/FDA Warning Letters

- Advanced Spine and Pain, LLC (03/28/2019)
 - Cancer, Alzheimer’s, schizophrenia, substance abuse, Parkinson’s, rheumatoid arthritis, & more
- Nutra Pure LLC (03/28/2019)
 - Alzheimer’s, neuropsychiatric disorders, PTSD, OCD, & more
- PotNetwork Holdings, Inc. (03/28/2019)
 - Liquid Gold Gummies & “blue CBD Crystals Isolate”
 - Alzheimer’s, Lou Gehrig’s disease, arthritis, diabetes, & more
- Rooted Apothecary, LLC (10/10/2019)
 - Teeth/TMJ – Essential Oil + CBD Infusion
 - Ears – Essential Oil + CBD Infusion

FTC CBD Warning Letters 09/09/2019

- 4Bush Holdings, LLC
- NuLife LLC
- Ocanna Co.

FTC CBD Warning Letters 09/09

- One company's website claimed CBD "works like magic" to relieve "even the most agonizing pain" better than prescription opioid painkillers. To bolster its claims that CBD has been "clinically proven" to treat cancer, Alzheimer's disease, multiple sclerosis (MS), fibromyalgia, cigarette addiction, and colitis, the company stated it has participated in "thousands of hours of research" with Harvard researchers.
- Another company's website claimed that CBD products are proven to treat autism, anorexia, bipolar disorder, post-traumatic stress disorder, schizophrenia, anxiety, depression, Alzheimer's disease, Lou Gehrig's Disease (ALS), stroke, Parkinson's disease, epilepsy, traumatic brain injuries, diabetes, Crohn's disease, psoriasis, MS, fibromyalgia, cancer, and AIDS. The company also advertised CBD as a "miracle pain remedy" for both acute and chronic pain, including pain from cancer treatment and arthritis.
- The third company's website promoted CBD gummies as highly effective at treating "the root cause of most major degenerative diseases, including arthritis, heart disease, fibromyalgia, cancer, asthma, and a wide spectrum of autoimmune disorders." The company also claimed its CBD cream relieves arthritis pain and that its CBD oil may effectively treat depression, PTSD, epilepsy, heart disease, arthritis, fibromyalgia, and asthma.

Looking Forward

- Increased enforcement on the federal and state levels.
- Stepped up FTC enforcement focusing on unsubstantiated disease claims.

Contact Information

Richard Cleland

Assistant Director

Division of Advertising Practices

Federal Trade Commission

rcleland@ftc.gov

(202) 326-3088



Developments in Enforcement of CBD and Cannabis Products

Office of the Indiana Attorney General
Attorney General Curtis T. Hill, Jr.
Chief Deputy – Aaron Negangard



Role of State Attorneys General

- **State attorneys general have a statutory responsibility to protect consumers from misinformation, scams and negligence.**
- **Our responsibility is to ensure that misinformation or scams are not being promoted by a particular industry.**



What is the applicable state law?

- **Deceptive Consumer Sales**
- **Potential Licensing Violations**



Deceptive Consumer Sales

- Indiana Deceptive Consumer Sales Act – Ind. Code 24-5-0.5 et seq.
 - Most States have a similar regulatory scheme if not more stringent.
- A business or person “may not commit an unfair, abusive, or deceptive act, omission, or practice in connection with a consumer transaction.” IC 24-5-0.5-3(a)
- Certain acts are specifically deceptive acts:
 - CBD oil (or other product) “has sponsorship, approval, performance, characteristics, accessories, uses or benefits it does not have which the supplier knows or should reasonably know it does not have.” IC 24-5-0.5-3(b)(1)
 - CBD oil (or other product) “is of a particular standard, quality, grade, style, or model, if it is not and if the supplier knows or should reasonably know that it is not.” IC 24-5-0.5-3(b)(2)
 - CBD oil (or other product) “has a sponsorship, approval, or affiliation in such consumer transaction the supplier does not have, and which the supplier knows or should reasonably know that the supplier does not have.” IC 24-5-0.5-3(b)(7)



Deceptive Consumer Sales

- **Remedies include:**

- Injunctive relief to stop sales or modify representations. IC 24-5-0.5-4(c)(1)
 - If an injunction is violated as determined by the court, a civil penalty of \$15,000 is imposed. IC 24-5-0.5-4(f)
- Restitution for consumers. IC 24-5-0.5-4(c)(2)
- Costs for the investigation and prosecution of action. IC 24-5-0.5-4(c)(4)
- Penalties of up to \$5,000 for each consumer transaction. IC 24-5-0.5-4(g)
 - If it is an incurable deceptive act, the penalty is not more than \$500 for each violation. IC 24-5-0.5-8



Licensing Violations

- **Licensing Violations – IC 25-22.5-1**

- The practice of medicine is considered holding oneself out to the public as “being engaged in” one or more of the following:
- (A) the diagnosis, treatment, correction, or prevention of any disease, ailment, defect, injury, infirmity, deformity, pain, or other condition of human beings;
- (B) the suggestion, recommendation, or prescription or administration of any form of treatment, without limitation;
- (C) the performing of any kind of surgical operation upon a human being, including tattooing (except for providing a tattoo as defined in IC 35-45-21-4(a)), in which human tissue is cut, burned, or vaporized by the use of any mechanical means, laser, or ionizing radiation, or the penetration of the skin or body orifice by any means, for the intended palliation, relief, or cure; or
- (D) the prevention of any physical, mental, or functional ailment or defect of any person.
- IC 25-22.5-1-1(a)(1)



Licensing Violations

- **Licensing Violations – IC 25-22.5-1**
- This is going to be a fact-specific inquiry that will turn on what the CBD oil provider is sharing with the public. If a specific person is stating that use of a CBD oil or other product will treat and/or cure a specific condition. Then it is possible that person could be prosecuted for practicing medicine without a license.



Licensing Violations

- **Licensing Violations – IC 25-22.5-1**

- In order for this type of case to proceed, the Office must receive a consumer complaint. IC 25-1-7-4
- Once a consumer complaint is received it would be investigated. IC 25-1-7-3
- A motion to cease and desist unlicensed practice would be filed before the Medical Licensing Board. IC 25-1-7-14(a)(1)
- If the Board finds there is unlicensed practice it can issue an order to cease and desist. IC 25-1-7-14(b)
- The cease and desist order is enforceable in the trial courts and a violation of the order is to be punished as a contempt of court. IC 25-1-7-14(d)
- A cease and desist order can also include an order to pay “consumer restitution to a person who suffered damages as a result of the activities that were the basis for the cease and desist order.” IC 25-1-7-14(h)
- The cease and desist order can also include an order to pay for the cost of the proceedings. IC 25-1-7-14(i)



Medicines Require Proof of Safety and Efficacy



- ✓ Multiple animal toxicology studies



- ✓ At least one hundred patient-years of data required



- ✓ Collection of all adverse events (side effects)
 - Mild/moderate/severe
 - Related and unrelated



- ✓ Studies... studies... and more studies
 - Drug/drug interaction
 - Food/drug interaction
 - Dependence/withdrawal
 - Renal or hepatic impairment
 - QT (cardiac)



- ✓ Monitoring of adverse events post-approval



Concerns with CBD

Clean Label Project CBD Study Results 2019

BRANDS TESTED INCLUDE:



WHAT WE TESTED FOR:

HEAVY METALS	PESTICIDES	PRESENCE OF THC	ACTUAL CBD CONTENT	PLASTICIZERS
4 (TOTAL ARSENIC, LEAD, CADMIUM, MERCURY)	86 (INCLUDING GLYPHOSATE)	✓	✓	9 (PHTHALATES, BPA & BPS)

CLEAN LABEL PROJECT TESTED THE FOLLOWING CBD PRODUCTS

242 Total



WHAT WE FOUND:

HEAVY METALS		PESTICIDES			
<p>TOPTEN BRANDS AVG</p> <p>34</p> <p>PARTS PER BILLION (PPB) OF LEAD</p>	<p>FLINT MI DRINKING WATER CRISIS¹ AVERAGED</p> <p>23</p> <p>PARTS PER BILLION (PPB) OF LEAD</p>	<p>PROPICONAZOLE A FUNGICIDE World Health Organization² MODERATELY HAZARDOUS TO HUMAN HEALTH</p>	<p>PYRIMETHANIL A FUNGICIDE World Health Organization² SLIGHTLY HAZARDOUS TO HUMAN HEALTH</p>	<p>AZOXYSTROBIN A FUNGICIDE World Health Organization² UNLIKELY HAZARDOUS TO HUMAN HEALTH</p>	
PRESENCE OF THC		ACTUAL CBD		PLASTICIZERS	
<p>THC-FREE DOES NOT ALWAYS MEAN FREE OF THC</p> <p>THC?</p>	<p>45% OF CBD PRODUCTS HAD MEASURABLE LEVELS OF THC</p>	<p>OVER 30% OF CBD PRODUCTS WERE OFF IN CALCULATING THEIR CBD CONTENT AND HAD GREATER THAN +/- 20% CBD DECLARED ON THE LABEL</p>	<p>ONE PRODUCT HAD 700% OF THE CBD DECLARED ON THE LABEL</p>	<p>WHAT IS A PHTHALATE? A CHEMICAL ADDED TO PLASTIC TO MAKE THEM BENDABLE</p>	<p>AVG AMOUNT WAS 1,091 PARTS PER BILLION (PPB)</p> <p>THIS IS 3X MORE THAN THE AVERAGE AMOUNT FOUND IN THE CONSUMER PRODUCT CATEGORY</p>
<p>100% OF PRODUCTS MAKING THC-FREE CLAIMS THAT ACTUALLY CONTAINED AT LEAST TRACE LEVELS OF THC WERE "FULL SPECTRUM" PRODUCTS</p>		<p>10 PRODUCTS HAD NO CBD AT ALL</p>		<p>PHTHALATES ARE LINKED TO ENDOCRINE DISRUPTORS KIDNEY DAMAGE AND REPRODUCTIVE HARM</p>	

¹ A 2015 Virginia Tech study of 271 Flint, Mich., homes, Frank Pompa, USA Today. https://www.who.int/ipcs/publications/pesticides_hazard/en/



How Much is .03 THC?

The 0.3% limit on hemp derived products in solution legally supports the sale of [2.7 mg THC](#) per milliliter. In a 30 milliliter bottle of CBD oil— a common retail unit— there would be [81 mg of THC](#)

One 4-gram CBD gummy (sold at retail in 30-count jars) could contain [12mg of THC](#) and still fall below 0.3% THC

According to a recent study performed at Johns Hopkins University, marijuana-infused brownies containing [10 mg of THC](#) resulted in a psychoactive drug effect in adults

Based on a recent publication, the average marijuana joint contains 320 mg of marijuana. Given Colorado's average THC potency for flower of 19.6%, the average joint in the state contains [63 mg of THC, of which about 17 mg actually enters the body](#)

Oregon's recreational marijuana laws prohibit any single serving of an edible marijuana product containing more than [5 mg of THC](#); and any whole edible product containing more than [50 mg of THC](#)

The FDA recommends a starting dose of [2.5 mg of THC](#) for prescription THC (Marinol).

Within Epidiolex – the only FDA approved botanically-derived CBD medication – the THC content is [10mg in 100ml](#)

A 30 milliliter bottle of CBD oil— a common retail unit— could contain **81 mg of THC** and still fall below 0.3% THC



One 4-gram CBD gummy (sold at retail in 30-count jars) could contain **12mg of THC** and still fall below 0.3% THC

State recreational marijuana laws (OR) prohibit more than **5 mg THC/serving; 50 mg THC/product**



FDA recommends a starting dose of **2.5 mg of THC** for prescription THC; **81 mg of THC= 32 doses**



The average marijuana joint in Colorado contains **63 mg of THC but only about 17 mg enters the body from smoking the whole joint**



How much is 0.3% THC?

Ways to measure 0.3%:

w/w (weight by weight of API) : percentage of THC to the total Active Pharmaceutical Ingredient (the sticky extract or white CBD crystalline powder)

w/v (weight by volume of product): percentage of THC to the total volume of the product ($\text{gm/ml} \times 100 = \%$)

w/w of the finished product: percentage of THC to the total weight of the finished product (wt of liquid/ml X #ml X 0.003=mg)

One 4 gram gummy = $4,000\text{mg} \times 0.003 = 12 \text{ mg THC}$

w/w 30 ml CBD in oil = $920\text{mg/ml of oil (specific gravity)} \times 30\text{ml in a bottle} \times 0.003 = 82 \text{ mg THC}$

w/v 30 ml CBD oil = $85 \text{ mg THC} (0.85\text{gm}/30\text{ml} \times 100 = 0.3\%)$



Contact Information:

Aaron Negangard

Chief Deputy Indiana Attorney General

anegangard@atg.in.gov

812-584-5995





DuaneMorris®

www.duanemorris.com

FDA and Cannabis: Striking the Balance Between Protecting the Public Health and Consumer Demand

Rick Ball

December 12, 2019

©2019 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.

Duane Morris – Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Taiwan | Boston
Houston | Austin | Hanoi | Ho Chi Minh City | Shanghai | Atlanta | Baltimore | Wilmington | Miami | Boca Raton | Pittsburgh | Newark | Las Vegas | Cherry Hill | Lake Tahoe | Myanmar | Oman
Duane Morris – Affiliate Offices | Mexico City | Sri Lanka | Duane Morris LLP – A Delaware limited liability partnership

Presenters



Frederick R. Ball | frball@duanemorris.com
Trial and FDA Regulatory Compliance Partner and
Team Lead for the Life Sciences and Medical
Technologies Group | 857.488.4240

Duane Morris' Cannabis Practice Group

- Multi-Disciplinary: Real estate, corporate, banking/finance, including PE/VC, real estate, healthcare, intellectual property, life sciences, litigation, regulatory, taxation
- Industry-Wide: Core and ancillary cannabis and hemp companies, including growers, processors, dispensaries, and infused-product manufacturers, real estate developers, universities and university research centers, raw materials companies, and investors.
- Full-Service: Permit applications, capital formation and financing, regulatory advice, real estate transactions, IP protection
- Thought Leaders: Blogs, Webinars, Speaking engagements - www.duanemorris.com



Standard Disclaimers

- The opinions expressed here are mine and should not be attributed to Duane Morris or FDLI
- Nothing in here is intended as legal advice
- I am not your lawyer. But I would like to be.
- If you have a questions ask. I will do my best to answer or I will make one up.



DuaneMorris®

www.duanemorris.com

Current Landscape for Cannabis

©2019 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.

Duane Morris – Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Taiwan | Boston
Houston | Austin | Hanoi | Ho Chi Minh City | Shanghai | Atlanta | Baltimore | Wilmington | Miami | Boca Raton | Pittsburgh | Newark | Las Vegas | Cherry Hill | Lake Tahoe | Myanmar | Oman
Duane Morris – Affiliate Offices | Mexico City | Sri Lanka | Duane Morris LLP – A Delaware limited liability partnership

Cannabis-Derived Products Approved or in Clinical Trials

- Active Pharmaceutical Ingredient (API)
 - CBD
 - Epidiolex
 - Sativex
 - Zygel
 - THC
 - Marinol
 - Syndros

FDA's Concerns

- Safety
 - Not enough data
 - Current data is mostly anecdotal
 - Effects based on mode of delivery
 - Interaction with other drugs or substances
- Continuing to provide incentive for drug development with CBD or CBD-derived compounds

FDA's Current Position

- **Drugs** – To make therapeutic claims need pre-market approval
- **Dietary supplements** – not an option due to formal clinical studies conducted with CBD API and no New Dietary Ingredient Notice Submitted
- **Food** – Not currently recognized as Generally Recognized as Safe (GRAS)
- **Cosmetics** - not currently prohibited or restricted (unless therapeutic claims made)
- **Animal products** – essentially same as above

State-Specific Regulations

- A number of states have specifically prohibited the use of CBD in foods, such as Massachusetts, Washington, and North Carolina.
- For example, Massachusetts prohibits the introduction of CBD into foods, dietary supplements and other consumables
- States and even individual municipalities have unique permitting and licensing requirements
- Some states have inspection and testing programs



DuaneMorris®

www.duanemorris.com

Advertising and Promotion

©2019 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.

Duane Morris – Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Taiwan | Boston
Houston | Austin | Hanoi | Ho Chi Minh City | Shanghai | Atlanta | Baltimore | Wilmington | Miami | Boca Raton | Pittsburgh | Newark | Las Vegas | Cherry Hill | Lake Tahoe | Myanmar | Oman
Duane Morris – Affiliate Offices | Mexico City | Sri Lanka | Duane Morris LLP – A Delaware limited liability partnership

Who Regulates Promotion and Advertising of Products?

- FDA
- FTC
- National Advertising Division of the Better Business Bureau
- Each state has its own laws

“Label” vs. “Labeling”

- “**label**” - a display of written, printed, or graphic matter upon the immediate container of a product
- “**labeling**” - anything a company say about a product it manufactures, distributes, or promotes, including directions for use, promotional material, websites, videos, conference presentation material, social media, etc.

What Constitutes Promotion

- Sales Rep initiated discussions about a product
- Product information or materials proactively provided by, or on behalf of, Manufacturer or Distributor
- Web-based materials created by the Manufacturer or Distributor
- Video created by the Manufacturer or Distributor
- In some cases, may include promotion by third-parties (e.g., non-affiliated distributors)

What is Advertising?

- No specific definition
- Examples include:
 - Print periodicals, such as journals, magazines, and newspapers
 - Broadcast media, such as television and radio, as well as through telephone systems

Key Factors

- **“Net Impression”** – message communicated by all elements of the piece as a whole
- Important to have an internal review processes or have outside counsel ensure:
 - *Materials are in line with marketing strategies*
 - *Are accurate and*
 - *Comply with applicable laws and FDA regulations*

Marketing of CBD-Derived Products

- FDA regulates CBD-derived products distributed, marketed, or sold **interstate or intrastate**
- FDA **was** exercising **enforcement discretion** for hemp-derived CBD products distributed, marketed, or sold **intrastate** that comply with state and local laws and regulations

States Also Regulate Marketing of CBD-Derived Products

- Use of child-resistant, tamper-evident, and light-resistant containers
- Statement of percent of THC be included on the label (sometimes to be calculated by a laboratory that did sampling and testing of the product)
- Certification that the THC level is below 0.3% be included on the label.
- Warnings, such as “This product is derived from hemp and could contain THC. Keep out of reach of children.”

Cautions in Using Social Media

- Truthful and non-misleading (even for social media with character space limitations)
- Company is responsible for material on its sites and user-generated content that it solicits or influences
- *Testimonials* – statement by third parties will be attributed to you if you control the site.

Cautions in Using Social Media (cont.)

- *Have to monitor posts by third parties on your sponsored S.M. sites*
 - Be careful with your Key Opinion Leader statements
 - Consider “PharmaWall” type software that allows you to monitor posts on Facebook before they go up
 - Disable comments (if possible)
- *“Double posts”* – third party poster on your social media site attaches an article about your product that contains unapproved uses or incorrect risk information – you’re responsible

Other Lessons from Social Media WLs

- FDA will follow the links – in other words, they won't just look at your website, but will look at all internet-related statements ... which leads them to social media
- Be careful with metatags
- Make sure the site is down if you say you've stopped improper claims
- Adverse event information – you must follow up on it, but that can be difficult

Endorsements or Testimonials

- Any advertising message that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser
 - must reflect the honest opinions, findings, beliefs, or experience of the endorser
 - cannot “convey any express or implied representation that would be deceptive if made directly by the advertiser.”

Endorsements or Testimonials (cont.)

- Cannot be presented out of context or reworded to distort the endorser’s opinion or experience with the product.
- Any connection between the endorser and advertiser that “materially affect[s] the weight or credibility of the endorsement” must be fully disclosed.
 - Remuneration need not be in the form of cash, but can include free products or services provided by, or on behalf of, the advertiser.

Consumer Endorsements

- Interpreted as representing that the product or service is effective for the purpose depicted in the advertisement.
- Must have adequate substantiation
- FTC has not found disclaimers regarding limited applicability of an endorser's experience to be effective.
- If “actual consumers” are not used then this must be conspicuously disclosed.

Liability for Use of Endorsements

- Any false or unsubstantiated endorsements or testimonials
- Failure to disclose a material connection with the endorser



DuaneMorris®

www.duanemorris.com

Enforcement

©2019 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.

Duane Morris – Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Taiwan | Boston
Houston | Austin | Hanoi | Ho Chi Minh City | Shanghai | Atlanta | Baltimore | Wilmington | Miami | Boca Raton | Pittsburgh | Newark | Las Vegas | Cherry Hill | Lake Tahoe | Myanmar | Oman
Duane Morris – Affiliate Offices | Mexico City | Sri Lanka | Duane Morris LLP – A Delaware limited liability partnership

Common Violations

- Promoting that the product will cure or mitigate a disease or symptom of a disease or affect the structure/function of the body
- Making unsubstantiated, comparative and/or superiority claims
- Promoting an unapproved use
- Omission of a material fact



Enforcement Tools

- Warning Letter
 - Strong language
 - Issued by FDA senior management
 - Sent to company officer (CEO)
 - Usually requires corrective action *e.g.* a recall and revision of labeling and promotional material

Enforcement Tools (cont.)

- Continuing or serious violations
 - Seizure of product
 - Consent Decree or Permanent Injunction
 - *Rigorous compliance program*
 - *Pre-clearance of future promotional materials*
- Criminal prosecution (and the *Park Doctrine*)
- Money payments (criminal fines, civil forfeitures, disgorgement of profits)



Initial Focus for CBD on Therapeutic Claims

- CBD stopped cancer cells/treats cancer
- CBD slows progression of Alzheimer's
- CBD has ability to treat the pain associated with migraines, fibromyalgia, IBS
- CBD effective for treating substance use disorders
- CBD used to avoid or reduce withdrawal symptoms

More Recent Focus

- Same
- But labeling as dietary supplement
- Also, FDA has stated it cannot make a determination that CBD is GRAS.
- Raises questions about whether a company can self affirm as GRAS

Consumer Protection/Fraud Class Action Suits

- Keeping accurate records concerning the concentration of CBD is important
- Be careful of claims like “vegan,” “gluten-free,” “non-THC,” “all natural,” “grown in USA,” “Made in USA”
- Warning letters are generating securities fraud cases and consumer class actions



Questions?

Seth A. Goldberg

sagoldberg@duanemorris.com

Frederick R. Ball

frball@duanemorris.com



Developments in Enforcement of CBD and Cannabis Products

Frederick (Rick) Ball, Partner, Duane Morris LLP and Treasurer,
FDLI Board of Directors

Richard Cleland, Assistant Director, Bureau of Consumer
Protection, Division of Advertising Practices, FTC

Aaron Negangard, Chief Deputy Attorney General, Indiana
Moderated by Libby Baney, Partner, Faegre Baker Daniels LLP