How Are Manufacturers Handling CBD Labeling and Marketing Issues?

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CBD Marketing Issues

Richard Cleland
Federal Trade Commission
Legal and Practical Issues in the Evolving World of Cannabis Regulation
November 19, 2019
Washington, DC

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

Basics 101

- The FTC has jurisdiction over the advertising of CBD products, and advertising includes websites.
- Section 5 of the FTC Act prohibits unfair or deceptive acts or practices in commerce and Section 12 of the FTC Act prohibits the false advertisement of food, drugs, cosmetics, devices, and services.

Basics 201

- 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.

Basics 301

- Claims that CBD can treat, cure, or mitigate a disease will likely require well-conducted, randomized, placebo-controlled human clinical trials.

Basics: Graduate Level

- If advertisers are going to rely on studies not conducted on their specific product, they will need to demonstrate that the CBD in the tested product is identical to the CBD in their product.

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 Warming Letters 09/09/2019

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

FTC CBD Warning Letters 09/09

- One company's website claims 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 states it has participated in "thousands of hours of research" with Harvard researchers.

- Another company's website claims 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 advertises CBD as a "miracle pain remedy" for both acute and chronic pain, including pain from cancer treatment and arthritis.

- The third company's website promotes 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 claims 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.

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Rules and Reality

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Objective

- Discuss laws/regulations as compared to realities of market
- Identify marketing trends and issues for hemp/CBD consumer products
- Explore impact of labeling and laboratory discrepancies and lack of standards
- Role of standard-setting organizations

"gap" between official law and social practices

FDA has concluded that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)].

Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement.

Under section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.

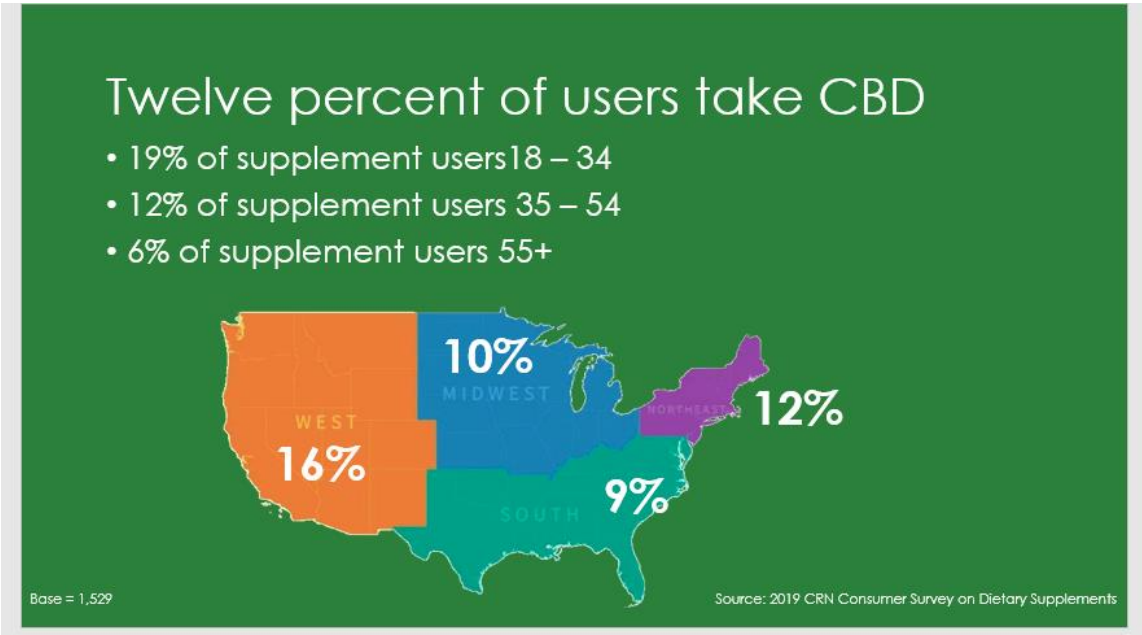
"gap" between official law and social practices

- Hemp/CBD is the top selling herbal supplement in the natural channel
  - 332% growth

*Herbal Market Report, American Botanical Council, 2018.

2019 CRN Consumer Survey

- 77 % of Americans report they consume dietary supplements
- 12% of supplement users consume CBD



Current Industry Environment

- Lack of full FDA enforcement
  - No facility inspections, label compliance, claims evaluation
- Responsible players on the sidelines
- State regs
- Many for-profit third party experts
- Standardized laboratory methods lacking
  - Matrix issues
- Self-regulation

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NSF International Brings Scientific Testing, Auditing and Certification to the Hemp and CBD Industry

September 18, 2019

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GROWERS
PROCESSORS / MANUFACTURERS
BRAND OWNERS

Cannabis Analytical Science Program

AOAC's Cannabis Analytical Science Program (CASP) is a forum where the science of hemp and cannabis analysis can be discussed and cannabis standards and methods developed.

Consumption of cannabis products is legal or becoming legal in a growing number of US states and in Canada. Consumable products include beverages, brownies, butter, chews, cookies, gummies, honey, edible oils, and more. CASP was formed to provide the consensus-driven standards and methods to promote accuracy in label potency claims and to address public safety issues such as pathogens and residual solvents.

With the passage of the Agriculture Improvement Act of 2018 (commonly known as the 'Farm Bill'), the hemp-derived CBD market is projected to reach $22 billion by 2022. CASP is developing analytical tools for accurate measurement of CBD in hemp plants and derived ingredients, in dietary supplements, and in pet foods.

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Take

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CBD Lawsuit Investigation: Are CBD Products Being Labeled Properly?

October 15, 2019

What's Going On?

Several class action lawsuits have been filed alleging that certain products do not contain as much CBD as their labels claim. Attorneys working with ClassAction.org are looking into whether additional CBD product manufacturers can be sued.

What You Can Do

If you bought one of these products, fill out the form on this page. You may be able to help get a class action lawsuit started.

Lowell Schiller, Nov. 7, 2019
CBD driving changes to DSHEA

- CBD issue puts a shining light on the mismatch between FDA's current resources and capabilities
- Dietary supplement industry continues to grow - add the rapidly growing CBD category into the matrix
- FDA resources do not match
- 4,000 dietary supplements on the market when DSHEA passed in 1994 and now there is an estimated 50,000 products + CBD products
- FDA claims to not have enough resources to protect the public from the high volume of shoddy products

- Tremendous pressure from lawmakers to reach a quick resolution on CBD but can't ignore FDA's current responsibility to regulate all supplements
- Schiller emphasized that FDA may need new regulatory tools like a **Mandatory Product Listing and new definition of 'Adulterated Supplement'**, to help regulate CBD as a dietary supplement.
- News Flash - FDA actively lobbying for new dietary supplement regulations

Lowell Schiller, Nov. 7, 2019

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What keeps industry up at night?

- Lack of regulatory clarity
- State regulations
- Marketing departments want claims
- Product ‘gotcha’ testing
- Consumer drug testing
- Lack of access to normal things – Amazon ads, banking, retail shelf space, etc.
- Internet and bad actors defining category

Thank You

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CBD in OTC Drugs & Cosmetics
FDA Regulatory Issues

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November 19, 2019

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FDA Legal Framework for Drugs

Drug products containing CBD and marketed with health-related claims can be legally marketed if there is:

(1) An FDA-approved new drug application ("NDA") for Rx and some OTC drug products

Active ingredient(s), inactive ingredients, formulation, indication for use, manufacturing, labeling

OR

(2) An OTC drug monograph

Recognized as G*enerally safe and effective* ("GRASE")

May be marketed without FDA approval if all conditions set forth in regulations are met

OTC Drug Monographs

FDA regulations for categories drugs

- Active Ingredients and Concentration
  - *e.g.,* 21 CFR 347.10: **Skin protectants: *active ingredients***
    - Calamine, 1% - 25%
    - Cocoa Butter 50%-100%
- Indications for Use
- Labeling
- Other Conditions for OTC drugs to be GRASE
  - *e.g.,* 21 CFR 330.1(d) ***Advertising*** "The advertising for the product prescribes, recommends, or suggests its use only under the conditions stated in the labeling."

Lip Protectant Labeling

(a) *Statement of identity:* “Skin protectant,” “lip protectant,” or “lip balm” (optional, may add dosage form, *e.g.,* “cream,” “gel,” “lotion,” or “ointment”).

(b) *Indications:* “temporarily protects minor: [bullet]1 cuts [bullet] scrapes [bullet] burns” (optional: “helps prevent and”) “temporarily protects” (optional: “and helps relieve”) (optional: “chafed,”) “chapped or cracked lips”

(c) *Warnings:* “For external use only”; “When using this product [bullet] do not get into eyes”

» 21 CFR 347.50

CBD in OTC Drugs

There are no OTC monographs permitting the use of CBD as an active ingredient.

OTC Drug Products May Contain Any Suitable Inactive Ingredient

"The product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity." 21 CFR 330.1(e)

- *As determined by each manufacturer*
- *Subject to FDA inspections*

CBD in OTC Monographed Drugs

- CBD is permitted as an inactive ingredient in OTC drug products only if it is:
  - *Suitable*
  - *Safe in the amounts administered an*
  - *Does not interfere with effectiveness*
  - *Does not interfere with suitable tests or assays to determine professed standards of identity, strength, quality, and purity*

Cosmetics

“Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients.”

Therefore, as a cannabis-derived ingredient, CBD can legally be incorporated into an OTC topical formulation.

"FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers" (Sept. 30, 2019), *available at*, https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd.

Cosmetics in OTC Drug Products?

Inactive ingredients in OTC topical formulations can be suitable for a cosmetic purpose.

If CBD has a cosmetic purpose, can it be used as an inactive ingredient in an OTC drug product?

More To Come

In the meantime, let’s discuss.

Thank you.

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