Cannabis and Cannabinoid Research
Volume X, Number X, 2020

DOI: 10.1089/can.2019.0101

Labeling of Cannabidiol Products: A Public Health Perspective

Jamie Corroon,[1,2,*] Douglas MacKay,[3] and William Dolphin[4,5]

Abstract

Introduction: Interest in the therapeutic use of cannabidiol (CBD) has reached a fever-pitch in recent months, as CBD-containing products appear everywhere from online retailers to grocery stores and gas stations. The widespread availability of hemp-derived CBD products is confounding given that CBD is a U.S. Food and Drug Administration (FDA)-approved drug, and thus precluded from being added to food and beverages, or included in dietary supplements. The use by manufacturers of disease-related claims on marketing materials and product labels, along with the federal legalization of hemp in December 2018, has created political pressure on FDA to promulgate regulations.

Conclusions: Accurate and informative labeling of hemp and hemp-derived CBD products is an important public health issue. FDA-regulated product labels are considered an essential tool for protecting consumers and enabling informed decision-making. Untruthful or unsubstantiated health-related claims, and unallowed Drug Claims, in marketing materials and on labels of CBD products may create harm by enticing consumers to forgo more evidence-based medical interventions. Furthermore, missing or inaccurate labeling of the amount of CBD, delta-9 tetrahydrocannabinol (THC), and potentially harmful contaminants such as pesticides, naturally-occurring yeast and mold or heavy metals may result in harm and/or lack of efficacy. Manufacturers of these products may reasonably be expected to understand and adhere to FDA regulations for labeling and marketing of food, dietary supplements and drugs, both over-the-counter (OTC) and prescription, even though FDA has interpreted federal law as excluding them from these categories. As manufacturers prepare for forthcoming regulations, a better understanding of the basic framework for FDA labeling and marketing regulations for food, dietary supplements and drugs is warranted.

Keywords: Cannabis; marijuana; THC; CBD; Food and Drug Administration; marketing; regulation

Background

Cannabidiol (CBD) is one of more than a hundred cannabinoids found in *Cannabis sativa* L., a plant more well-known colloquially as marijuana or hemp.[1] CBD was first isolated in 1940 and characterized structurally in 1963.[2,3] Interest in the therapeutic use of CBD has reached a fever-pitch in recent months, as CBD-containing products appear everywhere, from online retailers to grocery stores and gas stations.

Widespread availability of hemp and hemp-derived CBD products is confounding, given the position of the U.S. Food and Drug Administration (FDA), which maintains that CBD is an approved drug,[4] and thus precluded from being added to food and beverages, or included in dietary supplements.[5] To date, FDA enforcement has been limited to sending warning letters to manufacturers, largely for mislabeling or misbranding their products as unapproved new drugs, or for making claims that a product is indented to treat a disease condition on labels and marketing materials (FDA considers all sales materials, including consumer testimonials used in marketing, to be extensions of the label).[6–8] Political pressure on FDA is mounting. The agency had initially indicated it would expedite its

[1]The Center for Medical Cannabis Education, Del Mar, California.
[2]Helfgott Research Institute, National University of Natural Medicine (NUNM), Portland, Oregon.
[3]Scientific and Regulatory Affairs, CV Sciences, Inc., San Diego, California.
[4]Communications Department, Americans for Safe Access, Washington, District of Columbia.
[5]Graduate School of Education and College of Arts and Sciences, University of Redlands, Redlands, California.

*Address correspondence to: Jamie Corroon, ND, MPH, The Center for Medical Cannabis Education, 428 8th Street, Del Mar, CA 92014, E-mail: jamie@corroon.com

deliberations regarding regulation of hemp-derived CBD products,[9] however, a late 2019 update promised only to inform stakeholders "as quickly as possible."[10]

The public health imperative

Accurate and informative labeling of CBD products is an important public health issue. Product labels, and associated marketing materials, provide vital information about that product's composition and ingredients, as well as the potential risks and benefits of use. Unsubstantiated health-related claims, and unallowed drug claims, on labels of CBD products may create harm by enticing consumers to forgo more evidence-based medical interventions. In addition, absence of disclosure of major food allergens or solvents or excipients, if present, would constitute misbranding; and inaccurate labeling of the amount of CBD, delta-9-tetrahydrocannabinol (THC), or potentially harmful contaminants such as pesticides, naturally occurring yeast and mold, or heavy metals may result in harm and/or lack of efficacy.

Manufacturers of hemp and hemp-derived CBD products intended to be sold and marketed as food or dietary supplements may reasonably be expected to understand and adhere to FDA regulations for labeling and marketing of such products, even though FDA has interpreted federal law as excluding them from these categories. Similarly, manufacturers of products intended to be sold and marketed as drugs must comply with a different, more rigorous, set of FDA regulations that are specific to that category.

What's in a Label?

In the United States, the label of FDA-regulated products, which include food, beverages, dietary supplements, drugs, and more, represents the product's identity card. Product labels provide important information about that product's composition and ingredients, as well as the potential risks and benefits of use. FDA-regulated product labels are considered an important tool for protecting consumers and enabling informed decision-making.[11]

Widespread mislabeling of hemp and *Cannabis* products has been documented by both independent researchers and the FDA and other organizations.[12,13] Underlabeling and overlabeling of both CBD and THC content have been reported. The actual contents of available products can vary considerably from what are disclosed on the label; sometimes no CBD is present at all. Inadequate label information also poses risks of unintended, unwitting, or overconsumption of THC, the primary intoxicating compound in *Cannabis*, as well as potentially harmful contaminants.

Identity and Composition

Identity

FDA regulations mandate that food, dietary supplements, and drugs prominently display a "statement of identity" as one of the dominant features of the principal display panel of the label. This descriptive statement is used to identify the product (e.g., "Crackers," "Cereal," "Herbal Supplement") and allow consumers to easily interpret its intended use (e.g., food for nourishment, a dietary supplement to supplement the diet, or a drug for therapeutic purposes). A "statement of identity" is also important for hemp-derived CBD products. While the statement "Dietary Supplement" is required for products intended to supplement the diet, statements that identify other forms of CBD products, such as "Vape cartridge," or "Ointment," may help consumers more easily identify products that are not intended to supplement the diet.

Composition

Declarations related to the principal constituents of a food, dietary supplement, or drug are made within FDA-regulated Fact Panels. Most FDA product category requires a Fact Panel (i.e., Nutrition Facts, Supplement Facts, and Drug Facts) on the label to convey the information required for the safe, informed use of the product. For food and dietary supplements, the "Serving Size" and the "Servings Per Container" must also be stated within the Fact Panel. For prescription and over-the-counter (OTC) drugs, the active ingredients per dosing unit (e.g., tablet, capsule, and packet) and adequate directions for use are stated in the Drug Fact panel. The presence of Fact Panels on labels implies the product is in compliance with all FDA requirements for the corresponding category (i.e., food, dietary supplement, or drug).

CBD and THC content per serving is often intentionally absent from the label of hemp-derived CBD products marketed as dietary supplements. In the case of CBD, this omission is often intended to reduce the risk of enforcement actions by FDA or other federal agencies. In the case of THC, it may be due to the presumption that levels are low enough to be nonpsychoactive.

The presence of trace amounts of THC in hemp-derived CBD products is not unlike the presence of trace amounts of alcohol in certain beverages. For example, Kombucha products (i.e., fermented tea beverages) containing 0.5% or less alcohol by volume are not

Table 1. Allowable Amounts of Selected Ingredients

Labeling claim	Legal threshold
Hemp	0.3% dry weight THC
Kombucha and N/A beer	0.5% ABV
No calorie	5 calories per serving
Fat free	0.5 g per serving
Sodium free, salt free	5 mg per serving
Sugar free	1.0 g per serving

Source: FDA[22–25]

The 2018 Farm Bill defines hemp as the plant *Cannabis* with a THC concentration of not more than 0.3% by dry weight. The Farm Bill does not define a level that applies to finished consumer products. However, the Farm Bill explicitly maintains FDA's authority to determine a safe level for consumer products that it regulates such as foods, dietary supplements, cosmetics, and drugs.

ABV, alcohol by volume; THC, delta-9-tetrahydrocannabinol; FDA, Food and Drug Administration.

deemed alcohol beverages and not subject to Alcohol and Tobacco Tax and Trade Bureau regulations (Table 1).[14]

FDA allows "free from" claims for food products that contain trace amounts of sodium, fat, and sugar. However, hemp-derived CBD products should not carry a "THC-free" or similar claim until a specific legal threshold has been established. At least one consumer lawsuit has been filed based on a presumably faulty "THC-free" claim.[15] Similarly, if manufacturers use the term "Broad Spectrum" to suggest that a product is free of THC, then that needs to be defined in terms of an exact quantity and a specific analytical method.

Health-Related Claims on the Label

Health-related label claims are important because they communicate to consumers a given product's intended use, potential benefits and harms, and anticipated effects. FDA guidelines describe four categories of allowable health-related claims on labels of food, dietary supplements, and drugs. These include the following: (1) Nutrient Content claims; (2) Structure/Function claims; (3) Health claims; and (4) Disease claims. Each category of claims requires a certain level of evidence for substantiation of the claim that is in accordance with FDA regulations.

FDA Nutrient Content Claims

Nutrient Content claims simply characterize the level of a nutrient in a food, food component, or dietary ingredient, using terms such as free, high, and low (e.g., "low-calorie," "high-fiber," "fat-free"). Claims that use these terms are only allowed for nutrients with established Daily Values (i.e., Reference Daily Intakes or Dietary Reference Value). Nutrient Content claims can also compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and light (e.g., "reduced-sodium," "more fiber," "light" [referring to reduced fat]).[16] The use of Nutrient Content claims is grounded in nutrition science to avoid arbitrary use of these terms and to help consumers accurately identify and compare the nutritional value of foods.

The use of terms such as free, high, and low, while currently prohibited, may be helpful for hemp-derived CBD products when referring to biologically active compounds such as phytocannabinoids (e.g., "high in CBD," "THC free"). Standardized label terminology will reduce misuse of descriptive terms on labels and facilitate consistent communication to consumers. Industry stakeholders would benefit from engaging in an open process to reach consensus on harmonized constituent thresholds, as well as terminology for characterizing the composition of these products. Ultimately, appropriate terminology and thresholds should be negotiated with FDA and adopted by industry before being used in marketing.

FDA Structure/Function Claims

Structure/Function claims describe the role of a food or dietary ingredient in terms of its effect on the normal structure or function of the human body (e.g., "calcium builds strong bones," "fiber maintains bowel regularity"). Labels of foods and dietary supplements, as well as drugs, can display Structure/Function claims. Structure/Function claims for conventional foods are limited to physical attributes such as taste, aroma, or nutritive value (e.g., beef provides iron to support hemoglobin levels). For dietary supplements, Structure/Function claims may include non-nutritive support (e.g., supports memory and focus), general well-being, and claims related to nutrient deficiencies (e.g., vitamin C prevents scurvy). Structure/Function claims do not require premarket approval by FDA; however, the manufacturer must have substantiation that the claim is truthful and not misleading. A notification with the text of the claim must be submitted to FDA no later than 30 days after marketing the product.[17]

Claims related to a product's effect on normal function may help set expectations for consumers of hemp-derived CBD products. Nondisease-oriented claims (e.g., promotes a restful sleep or fosters stress resilience) can be supported with the appropriate scientific evidence, if available. Manufacturers should avoid referring to specific disease states (e.g., insomnia or anxiety), and instead use appropriate terminology that describes the anticipated effect for most users. This framework for claims making would encourage marketers to conduct research on unique

cultivars, formulations, and delivery technologies to determine if, in fact, different products lead to different effects.

It should be noted that the use of Structure/Function-type claims presents a risk of misinterpretation by consumers and misuse by manufacturers. The current use of Structure/Function claims for food and dietary supplements has been criticized because consumers may be confused and interpret a nondisease-oriented claim such as "promotes a restful sleep" as a therapeutic claim for a sleep disorder.[18]

FDA Health Claims and Drug Claims

Health claims and Qualified Health claims (Health claims) describe the relationship between a food or dietary ingredient and reduced risk of a disease or health-related condition (e.g., "adequate calcium throughout life may reduce the risk of osteoporosis"). Health claims pronounce disease risk reduction and therefore require FDA preauthorization and a higher level of substantiation. Alternatively, they may be based on an authoritative statement of the National Academy of Sciences, or a similar scientific body within the U.S. government that has responsibility for public health protection or nutrition research. When a product bears a label claim that states or implies the product is useful in diagnosing, curing, mitigating, treating, or preventing a disease, that claim is considered a drug claim and designates that product as a drug according to the FDA.[19]

Drug claims for prescription and OTC drugs are roughly analogous to Health claims for nondrugs but allow for statements beyond risk reduction (i.e., diagnosing, curing, mitigating, treating, or preventing). These claims are product-specific and subject to the most rigorous FDA premarket approval process, requiring both preclinical and clinical trials, including multiple phase 1–4 clinical trials. Results of these trials lead to clearly established indications and contraindications for use of the drug in specific diseased populations.[19]

FDA regulations prohibit any product that has not received premarket approval as a drug from making a Drug claim on its label or in marketing materials. Epidiolex™, an FDA-approved prescription form of CBD, can be marketed with Drug claims. Hemp-derived CBD products cannot.

Multiple manufacturers in the emerging CBD industry have made marketing statements that qualify as Health or Drug claims (Table 2). FDA has delivered cease-and-desist letters to more than 40 companies since 2015—the number more than tripled to 22 in 2019—for making such claims about their CBD products in labeling, including claims that they treat, or even cure, Alzheimer's disease, opioid withdrawal, pain, and anxiety.[20]

To underscore the importance of FDA preapproval of all Drug claims, FDA requires labels of dietary supplements that make any claims to include a disclaimer which states that the FDA has not evaluated the claim(s) and that the product "is not intended to diagnose, treat, cure, or prevent any disease."[21]

Conclusion

Accurate and informative labeling of hemp and hemp-derived CBD products is an important public health issue. Untruthful or unsubstantiated health-related claims, and unallowed Drug claims, in marketing materials and labels of CBD products may create harm by enticing consumers to forgo more evidence-based medical interventions. Furthermore, missing or inaccurate labeling of the amount of CBD, THC, and potentially harmful contaminants such as pesticides, naturally occurring yeast and mold, or heavy metals may result in harm

Table 2. Selected Examples of Labeling Claims Cited by Food and Drug Administration in Warning Letters

Company	Location of claim	Claim
Curale af, Inc.	Webpage	"CBD can successfully reduce anxiety symptoms, both alone and in conjunction with other treatments."
Advanced Spine and Pain, LLC (d/b/a Relievus)	Facebook	"Cannabidiol Fights Against Cancer CBD and other chemicals found in Cannabis have an anti-tumor effect and could be used to improve standard treatments. Please visit our website for more information!
Nutra Pure, LLC	Webpage	"Cannabidiol (CBD) Treats Neuropsychiatric Disorders"
PotNetwork Holdings, Inc.	Webpage	"Interestingly, however, in some lab studies, CBD has also shown the ability to kill cancer cells directly without the help of our immune system."
Green Roads of Florida, LLC	Webpage	"[CBD] has antipsychotic properties, which makes it very useful for treating bipolar disorder."
Natural Alchemist Alurent, Inc.	Webpage	"I was pleasantly surprised to find that CBD helped my arthritis…I have shared with my son and he states he is a big believer in CBD for. .. TBI [traumatic brain injury] after being acquainted with military personnel who have tried it."
Dose of nature	Facebook	"CBD May Reverse Brain Deficits in Parkinson's, Alzheimer's"

CBD, cannabidiol.

and/or lack of efficacy. Manufacturers of these products may reasonably be expected to understand and adhere to FDA regulations for labeling and marketing of food, dietary supplements, and drugs, both OTC and prescription, even though FDA has interpreted federal law as excluding them from those categories. As manufacturers prepare for forthcoming regulations, a better understanding of the basic framework for FDA labeling and marketing regulations for food, dietary supplements, and drugs is warranted.

Authors' Contributions

Design, research, and article writing, oversight—J.C. Design, research, and article writing—D.M. Research and article writing—W.D.

Author Disclosure Statement

J.C., ND, MPH, is the Medical Director at The Center for Medical Cannabis Education, a for-profit clinical and consulting entity. D.M., ND, has no conflicts to disclose. W.D., MA, is a paid consultant for Americans for Safe Access Foundation, a 501(c)3 nonprofit educational organization.

Funding Information

No funding was provided for this article.

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Cite this article as: Corroon J, MacKay D, Dolphin W (2020) Labeling of cannabidiol products: a public health perspective, *Cannabis and Cannabinoid Research* X:X, 1–5, DOI: 10.1089/can.2019.0101.

Abbreviations Used

ABV = alcohol by volume
CBD = cannabidiol
FDA = Food and Drug Administration
OTC = over-the-counter
THC = delta-9-tetrahydrocannabinol