Washington State
Liquor and Cannabis Board

NOTICE OF ADOPTION OF POLICY STATEMENT

Title of Policy Statement: Structure or Function Claims Concerning Marijuana [Cannabis] Infused Products – Policy Statement Number PS21-04.

Issuing Entity: Washington State Liquor and Cannabis Board

Subject Matter: This policy statement is intended to define medically compliant cannabis product structure or function claims to the extent possible, and establish a framework to guide structure or function label claim evaluation.

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Contact Person: Katherine Hoffman, Policy and Rules Manager, 360-664-1622

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Policy Statement

Title:	Structure or Function Claims Concerning Marijuana [Cannabis] Infused Products	*Number:* PS-21-04
References:	RCW 69.50.346 Chapter 246-70 WAC WAC 314-55-077 WAC 314-55-105	
Contact:	Katherine Hoffman, Policy and Rules Manager, WSLCB	
Phone:	360-664-1622	
***Email*:**	katherine.hoffman@lcb.wa.gov	
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Approved By:	Justin Nordhorn, Director Policy and External Affairs, WSLCB	

RCW 34.05.230 – Interpretive and policy statements

(1) An agency is encouraged to advise the public of its current opinions, approaches, and likely courses of action by means of interpretive or policy statements. Current interpretive and policy statements are advisory only. To better inform the public, an agency is encouraged to convert long-standing interpretive and policy statements into rules.

INTRODUCTION

Throughout this document, the term "cannabis" is used in the context of the statutory meaning of "marijuana" as defined in chapter 69.50 RCW.

This policy statement is intended to define medically compliant cannabis product structure or function claims to the extent possible and establish a framework to guide structure or function label claim evaluation.

This policy statement supersedes and replaces previous agency guidance concerning this topic.

SUMMARY

Structure or function claims are one of the ways to convey the potential purpose and benefit of a product. Federal law does not address a cannabis structure or function claim. However, cannabis is legal in Washington State, and the Washington state legislature suggests that like dietary supplements, cannabis processors may make structure or function claims for DOH compliant cannabis products as long as the claims are not claims relating to the treatment or

cure of disease, and the appropriate disclaimer is provided on the product labeling.[1] This places the WSLCB in the position of the FDA to establish criteria for the evaluation of cannabis product structure or function claims to assure such claims are not false or misleading consistent with Washington state statute.

In alignment with federal regulation and guidance, structure or function claims for DOH compliant cannabis products should be statements that describe the effect the product may have on the structure or function of the body. If the label or labeling of a product marketed as a DOH compliant cannabis product asserts a disease claim, or the structure or function claim is false or misleading, the product packaging and labeling will not be approved by WSLCB.

BACKGROUND

WSLCB routinely engages with cannabis licensees regarding the definition and application of "structure or function" claims as described in current cannabis packaging and labeling rules under WAC 314-55-105. Discussion centers around how to accurately describe "the role of a marijuana product intended to affect normal structure or function in humans, characterized by the means by which a marijuana product acts to maintain such structure or function" (WAC 314-55-105(1)(g)).

Currently, Washington State statute provides that labeling for Department of Health (DOH) compliant cannabis products may include claims that describe a product's intended role in maintaining a structure or function of the body. Such labels may also characterize the documented mechanism by which the product maintains a bodily structure or function. Statute also provides that labeling describing how a cannabis product maintains a structure or function of the body may not make disease claims, such as how the product may mitigate, treat, cure or prevent any disease.

Washington State statute does not define "structure or function" or "false or misleading."

STATUTORY AUTHORITY

RCW 69.50.346 describes required labeling content for all marijuana concentrates, usable marijuana, or marijuana-infused products sold at retail, with specific requirements for marijuana products identified by the Department of Health as being compliant marijuana product.

RCW 69.50.346(2)(a) provides that for marijuana products that have been identified by the department [of health] in rules adopted under RCW 69.50.375(4) in chapter 246-70 WAC as being compliant marijuana product, the product label and labeling may include a structure or function claim describing the intended rule of a product to maintain the structure or any

[1] *SB5298, supra note 8.*

function of the body, or characterize the documented mechanism by which the product acts to maintain such structure or function, provided that the claim is truthful and not misleading.

RCW 69.50.346(2)(b) provides that a statement made under (a) of this subsection may not claim to diagnose, mitigate, treat, cure, or prevent any disease.

CHAPTER 246-70 WAC describes Department of Health compliant products, including but not limited to product testing standards, labeling, and safe handling.

WAC 314-55-077(6) describes WSCLB cannabis recipes, product, packaging and labeling approval process and requirements.

WAC 314-55-105 describes cannabis product packaging and labeling.

WAC 314-55-105(1)(g) defines "structure and function claims" as “a description of the role of a marijuana product intended to affect normal structure or function in humans, characterized by the means by which a marijuana product acts to maintain such structure or function, or describe the general well-being from consumption of a marijuana product, consistent with the guidance provided in 21 U.S.C. Sec. 343[(r)](6).”

DISCUSSION

Structure or function claims are dietary supplement labeling claims that can be used to describe the potential effects of a dietary ingredient or singular substance on the structure or function of the human body. This category of claims was created by federal legislation contained in the Dietary Supplement Health and Education Act (DSHEA). The intent of DSHEA was to supply consumers with reasonably substantiated information that would allow them to make educated choices about their diet and health. Claims made under DSHEA were not intended to have the same weight and substantiation as the claims made for conventional prescription pharmaceuticals. Rather, they were proposed to fill the gap between consumer desire for over-the-counter supplements and foods, and rigorous and generally more potent and potentially “toxic” prescription medications. The legally mandated disclaimer, stating that the U.S. Food and Drug administration has not evaluated a structure or function claim often leads to misinterpretation. The logic of, indeed, need for structure or function claims is straightforward; however, of equal importance is that these products should be properly labeled, have accuracy in their ingredients, be free of contamination, be safe, and have a reasonable body of data that supports their efficacy.

Origin of Structure or Function Claims

The FDA recognizes three classes of claims that may be used on the labels of dietary supplements and foods: structure or function claims, nutrient content claims, and health

claims. Each has a different regulatory background and framework. A brief review of federal legislative history can help to explain some of the disparities in the regulation of the different types of labeling claims, particularly with respect to the special regulatory environment of structure or function claims on dietary supplements.

Before the 1980s, vitamins made up the majority of the dietary supplement market. At the time, herbal remedies played only a small role compared to the market for vitamins and were largely unregulated. Under the Reagan Administration's deregulation priorities, the FDA began to ignore many of the herbal remedies that did not come under their regulatory authority. Rather, the agency focused its attention on products that posed risk to human health and safety and made unbelievable or extreme disease claims.[2] As a result, there was an explosive growth in the herbal remedy industry and the scope of health claims escalated.[3] For example, St. John's Wort was expressly marketed to treat depression. Glucosamine condroitin was expressly marketed to treat arthritis. Echinacea was expressly marketed to treat the common cold and flu.[4]

This same period was also marked by considerable progress in understanding of the numerous relationships that can exist between nutrition and health. Efforts of private industry to capitalize on these discoveries resulted in a proliferation of nutrient contents claims, some of which were ambiguous and at times confusing. In 1984, the Kellogg Company in partnership with the National Cancer Institute argued that information on a potential link between high dietary fiber consumption and a reduced risk of cancer should be allowed on commercial products, and subsequently the Kellogg Company provided such information on All-Bran cereal boxes. While this type of claim was clearly prohibited on foods, the lack of subsequent regulatory action prompted other manufacturers to make similar health-related claims. Kellogg's actions ignited a new era of health and nutrition-related claims, which ultimately resulted in the development of a new regulatory framework: the Nutrition Labeling and Education Act (NLEA) of 1990.

The NLEA was important legislation in food and dietary supplement labeling background. It was intended to provide consumers with relevant information about food. To this end, it not only mandated nutrient content information on the labels of virtually all packaged foods but also gave the FDA the discretion to regulate health claims for foods and dietary supplements. The FDA defines health claims as "…a relationship between a food substance and reduced risk of disease or health-related condition." However, deregulation and congressional action placed a

[2] Margaret Gilhooley, Deregulation and the Administrative Role: Looking at Dietary Supplements, 62 Mont. L. Rev. 85, 90 (2001).
[3] Scott Bass, Dietary Supplements: Populism and Pirandello, in FDA: A Century of Consumer Protection 226-31 (Wayne L. Pines ed., 2006).
[4] Institute of Medicine of the National Academies, Complimentary and Alternative Medicine (2005).

one year moratorium on implementation of the NLEA. Once that year passed, the FDA returned to allowing health claims on dietary supplements.

It is important to note that the NLEA contains an express preemption provision that prohibits states from enacting label regulations and requirements that are not identical to the FDCA requirements.[5] According to the preemption provision, state labeling laws will be preempted if they set forth requirements that are "affirmatively different than the federal requirements."[6]

This FDA action sparked renewed debate over the regulation of dietary supplements and resulted in the passage of the DSHEA in 1994. The stated intention behind the DSHEA was to improve the health status of U.S. citizens by keeping dietary supplements affordable rather than requiring costly pre-market approval processes. The DSHEA provided the first legal definition of a dietary supplement (21 USC § 321 (ff)(1) and (2)(A) and (2)(C)):

> The term "dietary supplement" means:
>
> • a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid: (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
> • a product that is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form;
> • is not represented for use as a conventional food or as a sole item of a meal or the diet;
> • and is labeled as a dietary supplement.

Importantly, even though it clearly categorized dietary supplements as foods, it set different safety standards for them, establishing dietary supplements as a separate regulatory category. The act was also intended to allow manufacturers to make health related claims with a *reasonable* level of evidence (rather than a strict standard) to supply consumers with the information necessary to make educated choices about the nutrition, health, and preventive care for themselves and their families. For this purpose, it allowed dietary supplements to carry structure/function claims and other statements of nutritional support. According to the introduction to the DSHEA, dietary supplements were presumed to be safe over a wide range of intake. It has been argued that this was the justification for making the manufacturer

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[5] *See* 21 U.S.C. § 343-1(a) (2012) (creating provision wherein federal label laws preempt state label laws). The NLEA prohibits states from directly or indirectly establishing food label requirements that are not identical to the FDCA's food label requirements.

[6] Jennifer L. Pomeranz, *Litigation To Address Misleading Food Label Claims and the Role of the State Attorneys General*, 26 REGENT U.L. REV. 421, 429 (2014) (noting preclusion of state label laws "affirmatively different" than federal requirements) [hereinafter *Litigation To Address Misleading Food Label Claims*]; Termini, *supra* note 4, at 102 (stating preclusion of state regulations conflicting with certain enumerated FDCA sections, but not all). *But see* Termini, *supra* note 4, at 104-05 (asserting state action still encouraged to complement federal enforcement of regulations).

responsible for ensuring the safety of dietary supplements, while simultaneously leaving it up to the FDA to "reverse monitor" dietary supplements to determine whether products were not safe (adulterated) or misbranded based on false or misleading labels.

Linking Structure or Function Claims to Cannabis Products in Washington State

The federal Food, Drugs and Cosmetics Act (FDCA) prohibits marketing of food and dietary supplements containing cannabis.[7] The FDA has not approved any drug containing cannabis.[8] In addition, any substance, including cannabis that is intended for use as a drug is subject to FDA drug approval requirements. Although the FDA has approved only three cannabis-*derived* drugs and a fourth drug that contains cannabidiol (CBD), under federal law, cannabis manufacturers cannot make structure or function claims.

The Washington State Legislature brought the phrase into the regulated cannabis space in Engrossed Senate Substitute Bill (ESSB) 5298 (Chapter 393, Laws of 2019) by allowing "additional information on the labels and labeling of marijuana products to assist consumers in making purchases of these products."[9] The bill provided that only DOH compliant cannabis products could include product labeling with a structure or function claim describing the intended role of a product to maintain the structure or function or any function of the body. The legislature did not define structure or function in statute.

Further, while non-cannabis dietary supplements making structure or function claims need to be supported by competent and reliable scientific evidence along with a label disclaimer, the Washington State legislature did not explicitly extend this requirement to cannabis within the closed regulatory system. Instead, a licensee could make such a claim "provided that it is not false or misleading" and the product label contained a disclaimer specifically stating, "This statement has not been evaluated by the State of Washington. This product is not intended to diagnose, treat, cure, or prevent any disease." [10] This leaves it up to the WSLCB to review structure or function statements to assure they do not claim to diagnose, mitigate, treat, cure, or prevent any disease, or disease claims that are not "false or misleading" without defining either phrase.

[7] 21 U.S.C. 321
[8] FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)(https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd)
[9] RCW 69.50.346(2)(a).
[10] RCW 69.50.346(2)(a)

Analysis of Structure or Function Claim Application

21 U.S.C. Sec. 343(r) mentioned above regulates nutrition levels and health-related claims. 21 U.S.C. Sec. 343(r)(6) states that a statement for a dietary supplement may be made if the statement "claims a benefit related to a classical nutrient deficiency disease" and

> (i) "discloses the prevalence of such disease in the United States",
> (ii) "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans",
> (iii) "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function", or
> (iv) "describes general well-being from consumption of a nutrient or dietary ingredient."[11]

Such claims must be "truthful and not misleading."[12] It cannot claim to "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."[13]

The federal court's interpretation on the statute 21 U.S.C. Sec. 343(r)(6) is that to make a structure/function claim for dietary supplements, "manufacturers must meet three requirements:

1. The manufacturer must have substantiation that the statement is truthful and not misleading;
2. The statement must contain a prominent disclaimer that the FDA has not evaluated the statement and that the product 'is not intended to diagnose, treat, cure, or prevent any disease'; and
3. The statement itself may not 'claim to diagnose, mitigate, treat, cure, or prevent' disease."[14]

The second requirement is straightforward. The first and the third requirements are discussed below.

i. The manufacturer must have substantiation that the statement is truthful and not misleading

For the labeling of a dietary supplement to be considered truthful and nonmisleading, a structure/function claim cannot make disease claim that claims "to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases."[15] The FDA declines to adopt a "truthful and non-misleading" standard instead of the final rule that dietary supplement cannot carry

[11] 21 U.S.C. § 343(r)(6)(A).
[12] 21 U.S.C. § 343(r)(6)(B).
[13] 21 U.S.C. § 343(r)(6).
[14] *Greenberg*, 985 F.3d at 654.
[15] 21 U.S.C. § 343(r)(6).

unreviewed disease claims.[16] The FDA also declines to develop a list of "acceptable subclinical, pre-disease, and normal states" that may be used in structure or function claims.[17] However, it permits many examples of structure or function claims such as:

- Reduces joint pain[18]
- Relieves headache[19]
- Supports immunity[20]
- Promote heart health[21]

Generally speaking, "the FDA has blessed structure/function claims that use general terms such as 'strengthen,' 'improve,' and 'protect,' so long as the claims do not suggest disease prevention or treatment."[22]

The FDA also concluded that use of the terms "prescription" or "Rx" is misleading because these terms might imply the product is a drug.[23] Monograph claims on the over-the-counter drugs such as "reduces joint pain" do not exclude dietary supplements to make the same claim because not all drug claims are disease claims.[24]

The FDA regards the statutory requirement to substantiate claims important.[25] To substantiate a claim, "supplement manufacturers need only show evidence of an effect on a small aspect of the related structure/function; they need not provide evidence of an effect on the disease linked to that structure/function."[26] "Manufacturers are responsible for determining whether claims for their products can be appropriately substantiated, and to use only those claims for which they have substantiation."[27] The FDA would "expect manufacturers to provide a requester with contrary as well as supporting studies."[28] However, dietary manufacturers' monographs are not permitted under the FDCA.[29] Courts closely examine structure or function

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[16] *See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 Fed. Reg. 1000-01, 1002-02 (Jan. 6, 2000), https://www.westlaw.com/Document/IBC6CEAF02FBD11DAAE9ABB7EB80F7B3D/View/FullText.html?transitionType=Default&contextData=(sc.Default)&VR=3.0&RS=cblt1.0 [hereinafter *Regulations*].
[17] *Regulations, supra note 16,* at 1011.
[18] *Id.*
[19] *Id.*
[20] § 10:90. Dietary supplement health claims, 1 Food and Drug Admin. § 10:90 (2021), https://us.practicallaw.thomsonreuters.com/Document/I3320dce9364411dc8961eed6c013b0ce/View/FullText.html [hereinafter *FDA*].
[21] *Dachauer v. NBTY, Inc.*, 913 F.3d 844, 848 (9th Cir. 2019).
[22] *Greenberg*, 985 F.3d at 654-55.
[23] *Regulations, supra note 16,* at 1022.
[24] *See Id.* at 1011-12.
[25] *See Id.* at 1032.
[26] *Greenberg*, 985 F.3d at 655.
[27] *Regulations, supra note 16,* at 1012.
[28] *Id.* at 1032.
[29] *FDA, supra note 20*.

claims in the form of testimony offered by experts regarding product health benefit.[30] These testimonies should not promote a particular manufacturer or brand.[31]

However, substantiated claims are not feasible for cannabis products. The ways that cannabis may or may not have an effect on a related structure or function of the body is an emerging area of research that has yet to catch up with other non-cannabis dietary supplements where structure or function claims are more commonly used. For this reason, RCW 69.50.346(2)(a) provides that when cannabis products make a structure or function claim, labels must contain a disclaimer stating that, "This statement has not been evaluated by the State of Washington. This product is not intended to diagnose, treat, cure, or prevent any disease" based on a lack of evidence of an effect on a small aspect of the related structure/function for cannabis products.

i. <u>The statement itself may not claim to diagnose, mitigate, treat, cure, or prevent disease</u>

The line between a structure/function claim and a disease claim is that the structure/function claim merely describes an ingredient or nutrient's general role in the human body, while the disease claim describes the product's effect on the consumer's disease.[32]Any disease claim that claims to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases is not a permitted structure or function claim.[33] To assist in deciding whether a claim is or isn't a disease claim, federal regulation contains a definition for disease, and in guidance, offers 10 criteria[34] intended to help clarify the types of claims that may be made for dietary supplements without prior authorization or approval by FDA. Section 101.93(g) of the federal code defines disease as:

> ...damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

The 10 criteria are attached to this Policy Statement as Attachment A.

POLICY STATEMENT

Structure or function claims are one of the ways to convey the potential purpose and benefit of a product. No federal law addresses a cannabis structure or function claim. However, Washington State and the Washington state legislature suggests that like dietary supplements, cannabis processors may make structure or function claims for DOH compliant cannabis

[30] *Id.*
[31] 21 U.S.C. § 343-2(a)(2).
[32] *See Greenberg*, 985 F.3d at 656.
[33] 21 U.S.C. § 343(r)(6).
[34] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims

products.[35] This places the WSLCB in the position of the FDA to establish criteria for the evaluation of cannabis product structure or function claims to assure such claims are not false or misleading consistent with Washington state statute.

In alignment with federal regulation and guidance, structure or function claims for DOH compliant cannabis products should be statements that describe the effect the product may have on the structure or function of the body. If the label or labeling of a product marketed as a DOH compliant cannabis product asserts a disease claim as defined above, or the structure or function claim is false or misleading, the product packaging and labeling will not be approved by WSLCB.

Structure or Function vs. Disease Claims

It is not always possible to draw a bright line between structure or function and disease claims. Licensees should look at the ***objective*** evidence in their labeling to assess whether a claim *explicitly or implicitly* is a disease claim. For example, a statement may not mention a disease but may refer to identifiable characteristic signs or symptoms of a disease such that the intended use of the product to treat or prevent the disease may be inferred. The context of the statement, decided from information on the label and in other labeling, will determine if the statement is considered to be a disease claim. There are no specific verbs that constitute a disease claim. However, words such as "prevent," "mitigate," "diagnose," "cure," or "treat" would be disease claims if the context of their use *implied* an effect on a disease.

The following verbs are suggested when making a structure or function claim:

- Maintains
- Regulates
- Stimulates
- Promotes – Whether a claim for “promoting” structure or function is a disease claim will depend on the context and nature of the claim. For example, a claim that a product “helps promote digestion” would be a structure or function claim because it does not refer explicitly or implicitly to an effect on a disease state. A claim that a product promotes low blood pressure would be considered a disease claim. Statements using the word “promote” can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition.
- “Improves” often suggests some abnormality or deficiency that can be treated, so a claim to “improve” a structure or function of the body would be more likely to be a disease claim. On the other hand, a claim to improve memory or strength would be a permitted structure/function claim, unless disease treatment were implied.
- Words such as “augment,” strengthen,” “reduce,” “improve,” “modify,” “inhibit,” “protect,” or “defend” may be appropriate in some contexts, i.e., when the statements

[35] *SB5298, supra note 8.*

do not suggest disease prevention or treatment use. If, however, the use of these terms implies that the medically compliant cannabis product augments a particular therapy or drug action or otherwise suggests an effect on disease, the agency will consider the statement a disease claim.

WSLCB offers the following table as examples of what the FDA considers to be acceptable structure or function claims for dietary supplements and nonacceptable disease claims. The provision of these examples in this policy statement does infer any WSLCB approval of a DOH compliant cannabis product structure or function claim.

Examples of Acceptable Structure or Function Claims for Non-Cannabis Dietary Supplements	**Nonacceptable Disease Claim**
Antioxidants help neutralize free radicals, which in turn, reduce the incidence of cellular degeneration.	Protective against the development of cancer.
Helps support cartilage and joint function.	Reduces the pain and stiffness associated with arthritis.
Helps reduce muscle pain following exercise or over-exertion.	Improves joint mobility and reduces joint inflammation and pain" (rheumatoid arthritis).
Helps maintain cardiovascular function and a healthy circulatory system.	Relieves crushing chest pain (angina or heart attack).
Promotes relaxation.	Prevents depression.
Helps maintain healthy intestinal flora.	Help maintain the intestinal flora in people on antibiotics.
Helps promote urinary tract health.	Prevents benign prostatic hypertrophy. Improves urine flow in men over 50 years old.
Maintains bone health.	Prevents bone fragility in post-menopausal women" (osteoporosis).
Promotes health digestive function.	Heals stomach or duodenal lesions and bleeding (ulcers).
Helps to maintain cholesterol levels that are already within the normal range, or helps maintain a healthy cholesterol level. NOTE – FDA reviews all cholesterol claims to determine whether the labeling as a whole implies that the product is intended to lower elevated cholesterol levels. In such cases, FDA would consider the labeling to create an implied disease claim.	Lowers or reduces cholesterol.
Helps maintain/promote healthy collagen and cellular connectivity.	Prevents the spread of neoplastic cells (prevention of cancer metastases).
Promotes healthy respiratory function.	Relief of bronchospasm (asthma).
Helps promote or maintain healthy immune function.	Prevents wasting in persons with weakened immune systems (AIDS) (acquired immune deficiency syndrome).
Promotes/maintains normal heart functions.	Prevents irregular heartbeat (arrhythmias).

Use as part of your diet to help maintain a healthy blood sugar level.	Controls blood sugar in persons with insufficient insulin (diabetes).
Promotes/maintains normal or stable mood.	Herbal Prozac (depression).
Maintains healthy lung function.	Maintains healthy lungs in smokers (prevention of lung cancer and chronic lung disease).
Promotes optimal cellular health and functionality.	Helps maintain a tumor-free state (cancer prevention).
Promotes normal bone density.	Promotes normal bone density in post-menopausal women (osteoporosis).
Helps with mild mood changes.	Helps sooth the acute psychosis of pregnancy.
Helps with cramps and edema associated with the menstrual cycle.	Prevents severe depression associated with the menstrual cycle.
Helps to ameliorate mild memory problems associated with aging.	Prevents Alzheimer's disease or other senile dementias.
For the relief of occasional sleeplessness.	"Helps you fall asleep if you have difficulty falling asleep," and "helps to reduce difficulty falling asleep."
Supports the body's immune system.	Supports the body's antiviral capabilities.
"Occasional simple nervous tension," "nervousness due to common everyday overwork and fatigue," "a relaxed feeling," "calming down and relaxing," "gently soothe away the tension," "calmative," "resolving that irritability that ruins your day," "helps you relax," "restlessness," "nervous irritability," and "when you're under occasional stress, helps you work relaxed."	Helps relief nervous tension headache. Helps with anxiety disorders.
Improves absentmindedness (as long as the overall context does not imply treatment of Alzheimer's Disease).	Improves the symptoms of Alzheimer's Disease.
Reduces stress and frustration (as long as the overall context does not imply treatment of anxiety disorders).	Reduces the effects of anxiety disorders.

CONCLUSION

The FDCA prohibits marketing of food and dietary substances containing cannabis. Although the FDA has approved 3 cannabis-derived drugs, and a fourth drug that contains CBD, under federal law, cannabis manufacturers cannot make structure or function claims. No other state with a legalized cannabis market provides for such claims to be made. However, because cannabis is legalized in Washington State, such claims may be made for DOH compliant cannabis products to help consumers make informed decisions about the products they purchase.

Consistent with RCW 69.50.346(2)(a), WSLCB will evaluate structure or function claims to assure such claims are not disease claims and are not false or misleading in alignment with FDA guidance and established best practice for dietary supplements.

Attachment A

Criteria for determining if a statement is a disease claim[36]

Criterion 1: Claims an effect on a disease or class of diseases:

A statement is a disease claim if it mentions a specific disease or class of diseases. For example, a claim that a product is "protective against the development of cancer" or "reduces the pain and stiffness associated with arthritis" would be a disease claim.

A statement also is a disease claim if it implies that it has an effect on a specific disease or class of diseases by using descriptions of the disease state. Examples of implied disease claims are "relieves crushing chest pain (angina)," "improves joint mobility and reduces inflammation (rheumatoid arthritis)," or "relief of bronchospasm (asthma)."

Criterion 2: Claims an effect on characteristic signs or symptoms of disease using scientific or lay terminology:

How to determine if a particular claimed effect is a sign or symptom of a specific disease

The test of whether claimed effects are characteristic signs or symptoms depends on 2 questions: (1) Is the condition, to which the signs and symptoms refer, related to a disease; and (2) are the signs and symptoms referred to in the labeling characteristic of the disease and permit the inference that the product is intended to affect that disease.

Does it matter if I don't use every sign or symptom of a condition or if I use layman's terms instead of technical language?

No. The standard focuses on whether the labeling suggests that the product will produce a change in a set of one or more signs or symptoms that are characteristic of the disease. You can meet this standard using technical or layman's language and it isn't necessary that every possible sign or symptom is used.

How can I determine if a claim is about a sign or symptom that is "characteristic" of a disease?

You can look to medical texts and other objective sources of information about disease to determine if a label statement implies treatment or prevention of a disease. Some claims imply disease treatment or prevention because they are so intimately tied to a disease. For example, "inhibits platelet aggregation" or "reduces cholesterol" are such characteristic signs or

[36] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims

symptoms associated with stroke and cardiovascular disease and interventions to treat those diseases that any claim about them would be an implied disease claim.

Other signs or symptoms are associated with a wide range of disease and non-disease states and do not necessarily imply an effect on a specific disease. For example, although "improves absentmindedness" might imply treatment of Alzheimer's disease and "relieves stress and frustration" might imply treatment of anxiety disorders, both of these signs also are characteristic of non-disease states. So, if there is no context linking them to a disease, they would be appropriate structure/function claims.

For the claims that always imply disease, is there context that can make them appropriate structure/function claims, since platelet function and blood cholesterol also may be considered to be normal conditions?

Yes. There are many conditions that are "normal," but under certain circumstances are also disease claims. The federal rule states that such claims (for example, maintaining normal cholesterol levels) may be appropriate structure/function claims and would not imply a disease if the claim made absolutely clear that the claim is referring to structure/function claims that are already normal. This context would remove the inference to an effect on a structure/function that was abnormal (for example, "maintain cholesterol levels that are already in the normal range").

What kinds of words can be used that would not constitute implied claims about signs or symptoms?

No specific adjectives constitute a disease claim. Therefore, words such as "restore," "support," "maintain," "raise," "lower," "promote," "regulate," or "stimulate" might create an implied disease claim if, in the context they are used, they imply an effect on disease. Similarly, words like "prevent," "mitigate," "diagnose," "cure," or "treat" would be disease claims if the context of their use implied an effect on a disease.

Criterion 3: Claims an effect on a condition associated with a natural state or process:

What is meant by "a natural state or process?"

Some natural states or processes such as aging, menopause, and the menstrual cycle are not themselves diseases, but can be associated with abnormal conditions that are diseases.

What is the determining characteristic when a claim to effect these states is a disease claim?

The conditions associated with these stages or processes can vary from common, relatively mild abnormalities, for which medical attention is not required, to serious conditions that can cause significant or permanent harm if not treated effectively. Two criteria determine if such a condition will be considered a disease: (1) if the condition is uncommon; or (2) if the condition can cause significant or permanent harm. For purposes of the federal rule, a condition is

uncommon if it occurs in fewer than one-half of those experiencing that stage or process. A condition can cause significant or permanent harm if it must be treated effectively to prevent that harm and for which effective treatments are available.

Examples of acceptable structure/function claims are "mild memory loss associated with aging," "noncystic acne," or "mild mood changes, cramps, and edema associated with the menstrual cycle."

Examples of disease claims are "Alzheimer's disease or senile dementias in the elderly," "cystic acne," or "severe depression associated with the menstrual cycle."

Criterion 4: It is an implied disease claim because of the product name, formulation, use of pictures, or other factors:

1. Claims that are the name of the product.

Two principles form the basis for the distinction between product names that are structure/function claims and those that are disease claims. To be a structure/ function claim: (1) the name should not contain the name, or a recognizable portion of the name, of a disease; and (2) the name should not use terms such as "cure," "treat," "correct," "prevent," or other terms that suggest treatment or prevention of a disease. Additionally, context is very important here.

Names such as "CarpalHealth" or "CircuCure" are disease claims because they are implied disease claims for carpal tunnel syndrome and circulatory disorders, respectively. In some cases, whether a product name is a disease claim will depend on context. For example, "Soothing Sleep" could be considered a claim to treat insomnia, a disease, unless other context in the labeling makes clear that the claim relates to a non-disease condition, such as occasional sleeplessness.

2. Claims about product formulation.

Can I claim that my product contains an ingredient that is also used in some drug products?

If the ingredient has been regulated by FDA primarily as a drug (either over-the-counter or prescription) and is well known to consumers for its use or claimed use in preventing or treating a disease, you have made an implied disease claim when you list it in the ingredient list or make a claim that a product contains that ingredient. For example, aspirin, digoxin, and laetrile. Of course, an ingredient that is excluded from the definition of a dietary supplement under section 201(ff)(3) of the FD&C Act because it was approved as a drug before being marketed as a dietary supplement never can be used in a supplement.

3. Claims that use citations of publication titles.

Can I use citations of publications that relate to my product's intended use in labeling if the publication title or the journal name mentions a disease name?

Yes, but some limitations apply. If the citation implies treatment or prevention of a disease, it is a disease claim. Thus, if in the context of the labeling as a whole its presence implies treatment or prevention of disease (for example, by placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims), the citation is a disease claim.

If the citation is used in labeling, its context determines if it is a disease claim. A citation that is used in the bibliography section of labeling, is included in a balanced discussion of the scientific literature, is not excessively prominent relative to other citations, and provides legitimate support for a structure/function claim made for the product would not be a disease claim.

4. Claims that use the term "disease" or "diseased."

Can I make claims about health promotion and disease prevention?

Yes, you may make general statements about health promotion and disease prevention as long as the statement doesn't imply that your product can diagnose, cure, mitigate, treat, or prevent a disease. In general, if the statement identifies a specific disease or directly references the product or its ingredients, it would imply that the product itself has the effect and would be a disease claim.

An example of an acceptable claim is "a good diet promotes good health and prevents the onset of disease" or "better dietary and exercise patterns can contribute to disease prevention and better health."

An example of a disease claim is "Promotes good health and prevents the onset of disease" because the claim infers that the product itself will achieve the intended effect.

5. Use of pictures, vignettes, symbols, or other means.

Can I use pictures of organs or medical symbols on labels?

In general, any picture or vignette or other symbol can be used if it doesn't imply a disease. For example, pictures of healthy organs would constitute an appropriate structure/function claim while a picture of an abnormal tissue or organ would be an implied disease claim. As with other types of implied claims, it is the context of the total claim that is important.

Are there some symbols that are implied disease claims?

Yes. Some symbols, like the heart symbol, are so widely recognized as symbols for disease treatment and prevention that their use is ordinarily an implied disease claim. Symbols such as EKG tracings are also implied disease claims because they are strongly associated with heart

disease and the average consumer cannot distinguish a healthy tracing from an unhealthy one to provide context to remove the implied disease treatment or prevention claim. It would be an unusual circumstance in which the use of these two symbols would not be implied disease claims.

Can the Rx symbol be used without implying that the product is intended to treat disease?

In general, the use of the prescription drug symbol "Rx" or the use of the word "prescription" should not be interpreted automatically as a disease claim because not all prescription drugs are intended for disease conditions (some are for conditions that would not be considered to be diseases). However, the use of these terms on dietary supplements may deceive consumers into thinking they are purchasing a prescription drug without a prescription. Thus, the use of these two terms is misleading and will misbrand the product if, in the context of the labeling as a whole, the terms imply that the product is a prescription drug.

Criterion 5: Claims that a product belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease.

Certain product class names are so strongly associated with treating and preventing diseases that claiming membership in the product class constitutes a disease claim. Examples of such product classes are analgesics, antibiotics, antidepressants, antimicrobials, antiseptics, antivirals, or vaccines.

Some product classes may be associated both with diseases and with structure/function effects. In such cases, if it is clear from the context of the claim that the dietary supplement is represented as a member of the product class intended to affect structure/function and not disease, then the claim will not be a disease claim. That is, claiming to be a laxative, an anti-inflammatory, or a diuretic will not be a disease claim if there is context that makes clear that the intended effect of the product is on structure/function and not disease. For example, an appropriate product claim would be "diuretic that relieves temporary water-weight gain."

Criterion 6: Claims to be a substitute for a product that is a therapy for a disease.

A claim that a product is a substitute for a drug or other therapy for disease or has fewer side effects than a therapy for disease, is an implied disease claim. Such claims carry with them the clear implication that the dietary supplement is intended for the same disease treatment or prevention purpose as the therapeutic product. However, if a dietary supplement claims to be a substitute for a drug that is not intended to treat or prevent disease (i.e., a drug intended to affect the structure or function of the body), the claim comparing the drug and the dietary supplement would not be a disease claim.

Criterion 7: Claims to augment a therapy or drug intended to diagnose, mitigate, treat, cure, or prevent a disease.

A claim that a dietary supplement will augment a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent disease is a disease claim. A dietary supplement may state that it is useful in providing nutritional support, as long as that claim doesn't imply disease. In general, mentioning the name of a specific therapy, drug, or drug action will associate the claim with the intended use of the therapy, drug, or drug action and be a disease claim.

Criterion 8: Has a role in the body's response to a disease or to a vector of disease.

A claim that a dietary supplement fights disease or enhances disease-fighting functions of the body is a disease claim. Under this criterion, context and specificity are important. Claims such as "supports the body's ability to resist infection" and "supports the body's antiviral capabilities" are disease claims because the context of the claim is limited to the disease prevention and treatment capabilities. However, a claim that a product "supports the immune system" is not specific enough to imply prevention of disease because the immune system has both structure/function and disease fighting roles. A general claim of this type doesn't specifically focus the intended use of the product on the disease aspect of the system's function.

Criterion 9: Claims to treat, prevent, or mitigate adverse events associated with a therapy for a disease.

A claim that a product will affect adverse events associated with a therapy for disease is a disease claim if the adverse event is itself a disease. For example, "to maintain the intestinal flora in people on antibiotics" is a disease claim because the claim implies that the product will prevent pathogenic bacterial overgrowth (a disease condition) associated with antibiotic use. If the adverse event is not a disease, then this type of claim is acceptable. For example, a claim that a product is useful because it counterbalances the effect of a drug in depleting a nutrient or interfering with the metabolism of a nutrient would be an acceptable structure/function claim.

Criterion 10: Otherwise suggests an effect on a disease or diseases.

This provision of the regulation is intended to allow for implied disease claims that may not fit into the other nine criteria. This provision recognizes that a claim may be a disease claim based on its wording or on the context in which the claim appears on the product's label or labeling, even if not covered by the other nine criteria.