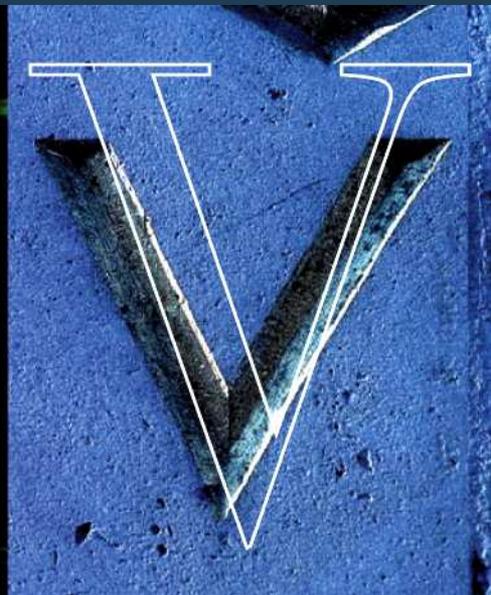
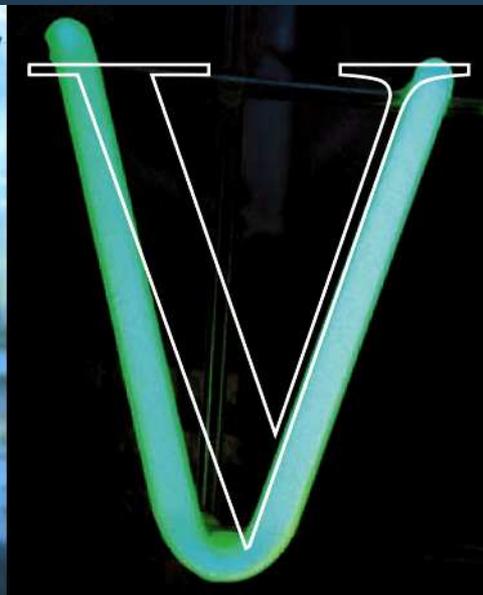
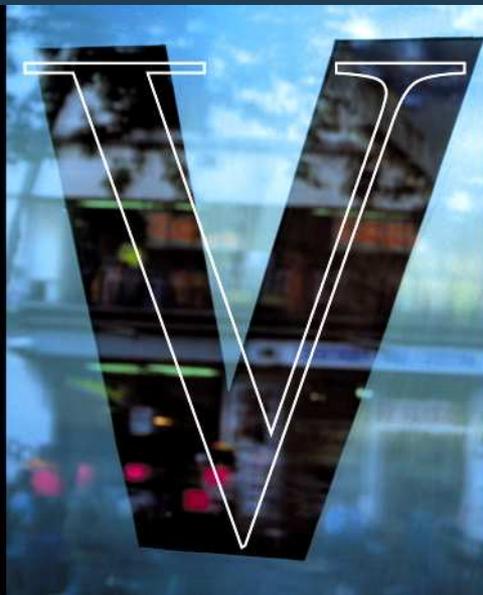
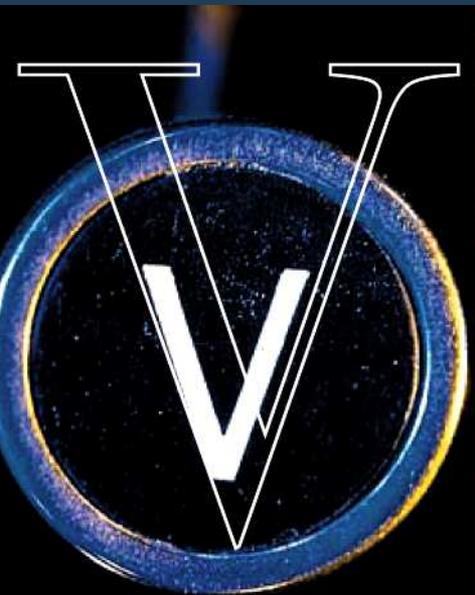


VENABLE[®]_{LLP}

Permissible vs. Impermissible Structure/Function Claims for Dietary Supplements



THE BASICS: What is a Structure/Function Claim?

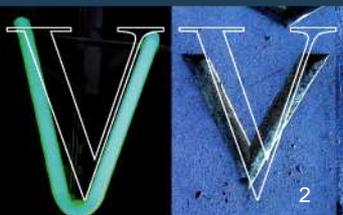
Structure/function claims can:

(1) describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans (“calcium builds strong bones”);

(2) characterize the action by which a nutrient or dietary ingredient maintains such structure or function (“fiber helps maintain digestive regularity”);

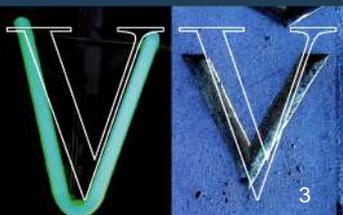
or

(3) describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread the disease is in the United States.



How do I know whether it is a permissible Structure/Function Claim, or a Disease Claim?

There are certain factors to consider when determining whether a particular claim is a permissible structure/function claim or an impermissible disease claim. They are based on FDA's eleven criteria.



Structure/Function Claims CRITERION ONE

A claim may not suggest that the product has an effect on a specific disease or class of disease.

Examples of **impermissible** claims under this criterion are:

- X** Reduces the pain and stiffness associated with arthritis.
- X** Helps alleviate the pain associated with migraine headaches.
- X** Helps alleviate the blues associated with emotional despair (i.e., despair = depression).

Examples of claims that **do not violate** this criterion are:

- ✓ Helps alleviate the occasional blue feeling everyone experiences from time to time.
- ✓ Helps maintain joint health and flexibility.
- ✓ Helps maintain a healthy heart.



Structure/Function Claims CRITERION TWO

A claim may not refer to a characteristic sign or symptom of a disease or class of disease.

Examples of **impermissible** claims are:

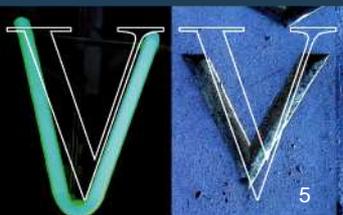
- X** Lowers serum cholesterol levels.
- X** Relieves painful joints.
- X** Lowers blood sugar levels.



HDL Cholesterol

Examples of claims that are **permissible** under this criterion are:

- ✓ Helps maintain cholesterol levels already within the normal range.
- ✓ Helps maintain proper joint function.
- ✓ Use as part of your diet to maintain healthy blood sugar levels.



Structure/Function Claims CRITERION THREE

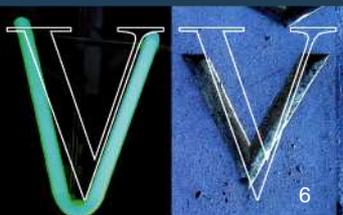
References to signs and/or symptoms of natural states are permissible as long they are not uncommon and would not cause significant harm if left untreated.

Examples of **impermissible** claims are:

- X** Helps alleviate BPH.
- X** Helps alleviate chronic constipation.
- X** Helps alleviate male potency problems (implied impotency claim).

Examples of **permissible** claims are:

- ✓ Alleviates mood swings and hot flashes associated with menopause.
- ✓ Alleviates occasional constipation.
- ✓ Promotes sexual arousal and performance.



Structure/Function Claims CRITERION FOUR

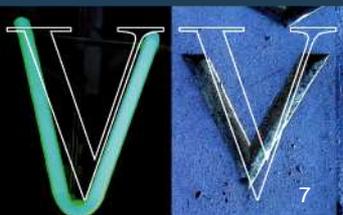
A claim may not be disguised as a product name.

Examples of **impermissible** product names are:

- X** Arthritis Formula
- X** Cho-less-terol
- X** Arthex
- X** Migraine Relief

Examples of **permissible** product names are:

- ✓ Mood Health
- ✓ Joint Flex
- ✓ Heart Health

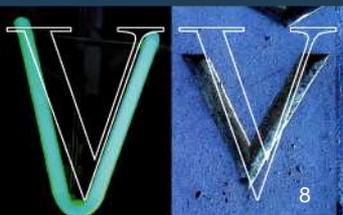


Structure/Function Claims CRITERION FIVE

A claim may not refer to a supplement's formulation if the statement suggests that the product is/was an FDA-regulated drug.

Example of an impermissible claim is:

“This product contains l-carnitine — formerly only available as a prescription drug”.



Structure/Function Claims CRITERION SIX

Citations to an article that refers to a disease in its title are permissible if the labeling taken as a whole does not imply a disease prevention or treatment claim.

- **To ensure compliance with this criterion, the article**
 - **should not be characterized in the copy;**
 - **should appear at the end of the promotional materials as part of a bibliography of other articles;**
 - **the article should be balanced; and**
 - **should not appear upon the product's label.**
- **Additionally, a bibliography that contains more than insignificant amount of articles that refer to a particular disease would be considered suspect by FDA and should be avoided.**



Structure/Function Claims CRITERION SIX (continued)

Impermissible Bibliography

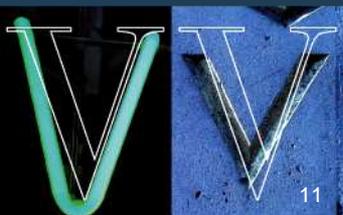
- Adams, J. *Daily consumption of green tea reduces the risk of cardiovascular disease.* 23 J. Amer. Nutr. 45-67 (2008).
- Bailey, K. *Antioxidants in green tea lower blood cholesterol levels.* 12 Food Sci. 34-56 (2007).
- Crane, H. *Green tea consumption in individuals at risk for heart disease.* 56 Nutr. Sci. 78-89 (2009).
- *Cholesterol.* Patient Guide, Physician's Desk Reference 2008.



Structure/Function Claims CRITERION SIX (continued)

Permissible Bibliography

- *Cholesterol*. Patient Guide, Physician's Desk Reference 2008.
- Bailey, K. *Antioxidants may lower blood cholesterol levels*. 12 Food Sci. 34-56 (2007).
- *Green Tea*. Natural Ingredients Quarterly (Fall 2008).
- Garth, B. *Antioxidant Properties of Green Tea*. 14 Amer. J. Med. 92-109 (2009).



Structure/Function Claims CRITERION SEVEN

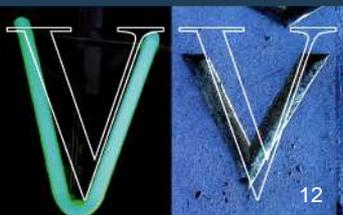
The use of the terms disease, diseases, antiviral, antibacterial, antiseptic, antibiotic, analgesic, diuretic, antidepressant, vaccine, analgesic, or any other word suggesting that the product belonged to a class of products intended to cure, treat, or prevent disease, is not permitted.

Examples of impermissible claims are:

- X** Stimulates the bodies antiviral capacity.
- X** Helps Individuals using antibiotics maintain normal intestinal flora.
- X** Helps alleviate depression.

Examples of permissible claims are:

- ✓ Helps maintain proper immune function.
- ✓ Helps reduce stress and tension.
- ✓ Restores intestinal flora.



Structure/Function Claims CRITERION EIGHT

The use of pictures, vignettes, symbols, or other means in a manner that would otherwise suggest the presence of a disease condition is not permitted.

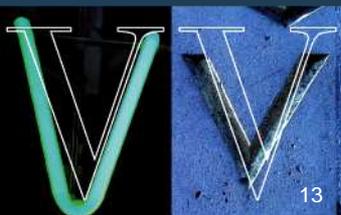


Risky Example: Picture of a hand with the joints highlighted in red may be considered an implied “disease” claim because the red highlight could be interpreted as a sign of pain or arthritis.

Alternative Example: Picture of a hand — standing alone — would probably not be considered a “disease” claim because it does not reference a particular endpoint — joints and pain.



(Exception: The preamble to the final rules indicate that use of the heart symbol on product label and labeling is an impermissible heart disease prevention claim.)



Structure/Function Claims CRITERION NINE

A claim may not suggest that the supplement or its ingredients belong to a particular class of drugs or is a substitute for a particular therapy.

Examples of impermissible claims are:

- X** Herbal antidepressant
- X** Helps maintain joint health without the use of NSAID's.



Structure/Function Claims CRITERION TEN

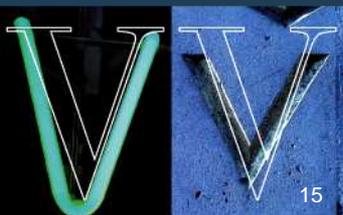
A claim may not suggest that a product is useful as a companion to regular drug therapy, or that it prevents or treats adverse events associated with a disease if the adverse events are also disease conditions.

Examples of impermissible claims are:

- X** Helps maintain blood sugar levels in insulin dependent people.
- X** Helps stimulate the immune system when undergoing chemotherapy.

Examples of permissible claims are:

- ✓ Helps maintain intestinal flora.
- ✓ Use as part of a healthy diet to help maintain healthy blood sugar levels.



Structure/Function Claims CRITERION ELEVEN

FDA adds a final catch-all criterion that prohibits the use of a claim that “otherwise” suggests a disease or disease condition.



Substantiation for Dietary Supplement Claims

On January 2, 2009 FDA finalized its guidance,
**Substantiation for Dietary Supplement
Claims Made Under Section 403(r) (6) of
the FFDCA.**

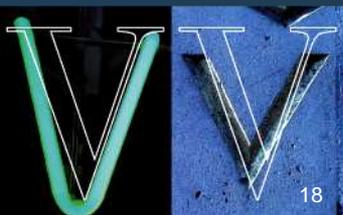
This guidance confirms FDA's reliance on many
of the same evidentiary standards applied by the
Federal Trade Commission.



Substantiation for Dietary Supplement Claims

Substantiation for dietary supplement claims must consist of “competent and reliable scientific evidence,” defined as:

tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.



Substantiation for Dietary Supplement Claims

Although FDA eschews a particular formula for the number and type of studies required to substantiate a claim, it suggests that advertisers consider:

1. The meaning of the claim(s) being made;
2. The relationship of the evidence to the claim;
3. The quality of the evidence; and
4. The totality of the evidence.

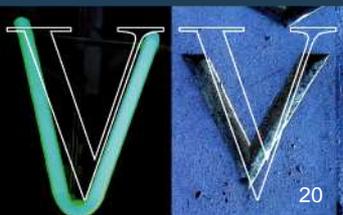
As well as accepted norms in the relevant research fields.



Substantiation for Dietary Supplement Claims

MEANING OF CLAIMS

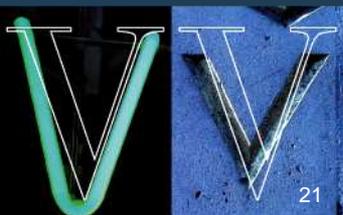
- Express and/or implied
- Need evidence for any reasonable interpretation
- Consumer understanding of claim



Substantiation for Dietary Supplement Claims

RELATIONSHIP BETWEEN EVIDENCE & CLAIM

- Do the studies identify a specific supplement or ingredient, along with the serving size and conditions of use?
- Are the serving sizes and conditions of use similar to the labeling conditions for and amounts in the supplement product?
- Is the studied population representative of the target market for the dietary supplement?
- The nature and specificity of the claim is very important in determining whether it has a strong enough relationship to the evidence. (E.g., “Crosses the blood-brain barrier to oxygenate the brain” vs. “Supports immune health.”)

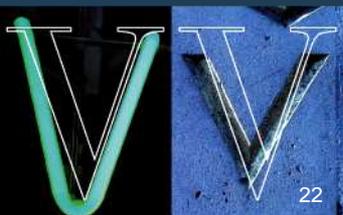


Substantiation for Dietary Supplement Claims

QUALITY OF EVIDENCE

- Study population
- Study design and conduct (e.g., presence of a placebo control and double blinding)
- Statistical analysis

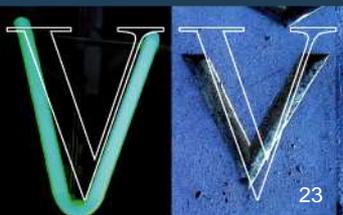
In general, accepted scientific and statistical principles are used to evaluate the quality of evidence.



Substantiation for Dietary Supplement Claims

TOTALITY OF THE EVIDENCE

- Both positive and negative evidence with regard to a claim must be considered.
- If there is negative evidence, does it outweigh the evidence in favor of a claim?
- Has the positive evidence been replicated in multiple studies?
- As a practical matter, could the claim be qualified in order to better reflect the balance of evidence?



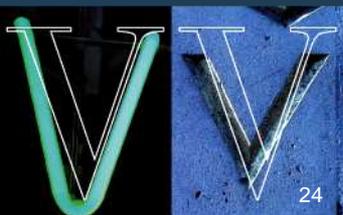
Technical Requirements: FD&C Disclaimer

The FD&C Act requires the following disclaimer to appear in connection with a structure/function claim:

“This/these claim(s) has/have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

Statement must also...

- ✓ Be at least 1/16 inch font size,
- ✓ Be bold,
- ✓ Be entirely enclosed inside a box,
- ✓ Be listed by itself, preferably on the same panel as claim or include a link to the claim.



Technical Requirements: 403(r)(6) Claim Reporting

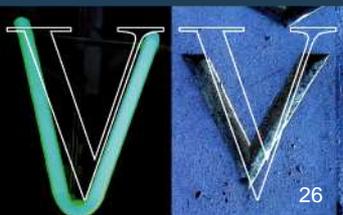
No more than thirty (30) days after a supplement bearing a structure/function claim is marketed, the manufacturer, packer, or distributor of the supplement must notify the FDA Office of Nutritional Products, Labeling, and Dietary Supplements.



Technical Requirements: 403(r)(6) Claim Reporting

The 30-Day Notification must include:

- (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;
- (2) The text of the statement itself (or statements);
- (3) The name of the dietary ingredient or supplement that is the subject of the statement, if not included in the statement; and
- (4) The name of the dietary supplement (including brand name) in whose labeling the statement appears.



Closing Thoughts

- Be sure to view claims in context
- Not all substantiation is equal
- Conduct claim assessment before campaign is complete



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