

SALESWATCH ONLINE™

NEWS IMPACTING YOUR BUSINESS

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THE NEW DIETARY SUPPLEMENT STRUCTURE/FUNCTION RULE

At long last, the FDA has promulgated a new regulation clarifying the permissible scope of dietary supplement claims that have an effect on a structure or function of the body ("structure/function" claims). The regulation attempts to differentiate what constitutes permissible structure/function claims from impermissible disease claims. This is the guidance that all dietary supplement marketers have been craving since the Dietary Supplement Health and Education Act ("DSHEA") was passed in 1994. Naturally, in the drafting process, FDA sought a broad interpretation of what constitutes a "disease", while industry fought for a more liberal definition. The result of this tug-of-war is the following regulation:

(f) Permitted structure/function statements. Dietary supplement labels or labeling may, subject to the requirements in paragraphs (a) through (e) of this section, bear statements that describe the role of a nutrient or dietary

ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

(g) Disease claims. (1) For purposes of 21 U.S.C. 343(r)(6), a "disease" is 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.

(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

- (i) Has an effect on a specific disease or class of diseases;
- (ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, us-

ing scientific or lay terminology;

- (iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;
- (iv) Has an effect on a disease or diseases through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

(C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

(E) Use of pictures, vignettes, symbols, or other means;

- (v) *Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;*
- (vi) *Is a substitute for a product that is a therapy for a disease;*
- (vii) *Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;*
- (viii) *Has a role in the body's response to a disease or to a vector of disease;*
- (ix) *Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or*
- (x) *Otherwise suggests an effect on a disease or diseases.*

21 C.F.R. § 101.93

Isn't it great the way lawyers can spit out the legal gobbledegook and then assume that the reader has a clue what was just said? Well, guess what - the FDA spent 50 pages explaining what the regulation means and how it will be applied, so if you didn't comprehend the rule by simply reading it (and believe me, *nobody* does, and if someone tells you they do, they are lying!), the following synopsis and examples should be helpful.

What the Rule Permits

Boiling the fat away, the rule permits supplement marketers to make a claim that their products affect the structure of function of the human body so long as the claims are not disease claims. The key is determining what constitutes a "disease claim." On this point, the rule provides that a disease claim exists if a claim states *or implies* that a product can be used to diagnose, mitigate, treat, cure, or prevent a disease. A "disease" is

damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunction.

Unfortunately, boiling the fat away hardly makes a dent in helping us comprehend whether or not a claim is a disease claim. Fortunately, the FDA has listed ten factors that it will consider to determine if a claim constitutes a disease claim, and it has given numerous examples of what will qualify as proper structure function claims. FDA has also stated that it will be developing additional examples of proper structure/function claims (this seems to be a concession by the FDA that even with the most detailed verbal interpretations of the rule, the examples are the only things that make sense!). Consequently, the ten factors, and the corresponding examples given by FDA are synthesized below.

The Ten Factors

If a dietary supplement claim satisfies one of the following ten factors, the FDA will deem it as evidence that the product is intended to treat, cure, prevent or mitigate a disease. In addition, one must always bear in mind the context in which the claim is made. While a claim may not make an express disease claim, the context in which the statement is made will be considered in every case. This is clearly and repeatedly emphasized in the comments to the rule. With that caveat, the ten factors are as follows:

i. Explicit or Implicit Statement that a Product has an Effect on a Disease or Class of Diseases

A statement will be a disease claim if a marketer explicitly or implicitly claims that its product has an effect or a disease or class of diseases. Thus, if a claim represents that a supplement will have an effect on a specific disease, the claim constitutes a disease claim. Therefore, one of the easiest rules to remember and follow is *never specify a disease by name in your advertising or labeling!* But that is

the easy part. Implied claims are equally problematic. The comments to the rule provide a number of examples of impermissible implied claims. They include the following:

Prohibited Implied Disease Claims ¹	Implied Disease
Relieves crushing chest pain	Angina or heart attack
Prevents bone fragility in post-menopausal women	Osteoporosis
Heals stomach or duodenal lesions and bleeding	Ulcers
Anticonvulsant	Epilepsy
Relief of bronchospasm	Asthma
Prevents wasting in persons with weakened immune systems	AIDS
Prevents irregular heartbeat	Arrhythmias
Controls blood sugar in persons with insufficient insulin	Diabetes
Prevents the spread of neoplastic cells	Prevention of cancer metastases
Antibiotic	Infections
Herbal Prozac	Depression
Improves joint mobility and reduces joint inflammation and pain	Rheumatoid arthritis. In addition, "improvement" connotes treatment because the system is in an abnormal state.

The key that marketers must recognize when dealing with implied claims is that the FDA will seek to determine what the objective intent of the marketer is when making a claim. Beware, however, because the FDA will place little credence in what a marketer claims to be its intent. Rather, the agency will look to the inferences that can be made from a variety of sources, including labels, labeling, advertising and promotional material.

Interestingly, and significantly, the final rule does not automatically consider reference to a body or a board such as the National Cancer Institute or the American Heart Association to create an implied disease claim. For example, marketers frequently wish to cite statistics from such bodies in their advertising. A common approach is: "According to the National Cancer Institute" The mere fact that the word "cancer" is used in the sentence does not automatically render the statement a disease claim. Rather, the claim will be

considered a disease claim only if, within the context of the total labeling, the statement can be reasonably understood to relate the product to the disease listed in the organization's name." By way of example, FDA would consider the statement "According to the National Cancer Institute, ingredient X protects smokers' lungs" to be a disease claim.²

ii. Claimed Effect On Signs or Symptoms of a Disease

Under this consideration, the FDA focuses on whether a marketer's claim suggests that a product will produce a change in the characteristic signs or symptoms of a specific disease or class of diseases. FDA will look to medical texts and "other objective sources of information" about diseases to determine whether a claim implies treatment or prevention of disease by listing the characteristic signs and symptoms of the disease or class of diseases. There are important qualifiers that are attached to this

approach that marketers must understand. They include:

- The standard may be met if the signs and symptoms are referred to either in technical or lay language;
- It is not necessary to mention every possible sign or symptom of a disease to meet the standard.
- The standard will be satisfied if the claim provides that a product will produce a change in a set of one or more signs or symptoms that are characteristic of the disease.³

Permissible Claims ⁴	Comment
Improves Absentmindedness	Does not imply treatment of Alzheimer's because absentmindedness is not as serious as the type of memory loss characteristically suffered by Alzheimer's patients.
Relieves Stress & Frustration	While these symptoms can be associated with some anxiety disorders, they are not the <i>characteristic</i> symptoms of those disorders. In addition, they are equally associated with many other nondisease states.
Helps Support Cartilage and Joint Function	This claim relates to maintaining normal joint function rather than treating joint pain.
Maintains healthy lung function.	No disease is implied or specified.
Helps maintain cholesterol levels that are already within the normal range.	If one's cholesterol levels are already within the normal range, the individual is not within a category that is normally recognized to be at risk for heart disease. If a claim is made to reduce, or normalize cholesterol levels, an implied disease claim will exist.

Impermissible Claims ⁵	Comment
Inhibits Platelet Aggregation	Although platelet aggregation is a normal function needed to maintain homeostasis, inhibiting platelet aggregation is a well-recognized therapy for prevention of stroke or heart attack.
For Joint Pain	"Joint Pain" is characteristic of arthritis.
Prevents bone fragility in postmenopausal women	Implies prevention of osteoporosis.
Maintains healthy lungs in smokers	Smokers are an at-risk population for lung cancer. Therefore, the claim implies lung cancer prevention.
Helps lower cholesterol <i>and/or</i> Promotes cholesterol clearance.	FDA takes the position that "lowering cholesterol" and "cholesterol clearance" are implied disease claims because they are linked to treating elevated cholesterol and preventing heart disease.

Again, the test to determine whether an implied claim is a disease claim is determined by the intent of the marketer. The FDA will take into consideration a number of things outside of the words used. It will consider the use of symbols, vignettes, or other forms of communication that suggest, within the context in which the claim is made, that a relationship exists between a supplement and a disease or health-related condition.

One area that has caused a great deal of confusion is the distinction between "health maintenance" claims and "disease" claims. After all, a statement that a product will maintain health certainly implies that it will prevent an abnormal state of health. On this point the FDA has indicated that health maintenance claims will be acceptable unless they imply that they will prevent or treat a specific disease or a disease that is closely associated with an at-risk population. For example, a claim that a product "maintains healthy lungs in smokers" implies the prevention of tobacco related lung cancer, whereas the statement "maintains healthy lung function" is an acceptable claim.⁶

iii. Conditions Associated with Natural States

One of the most hotly contested issues surrounding the proposed rules was the FDA's proposal to include natural states such as menopause, pregnancy, and menstrual cycles to qualify as diseases. Fortunately, the FDA has backed off from this position in the final rule. Rather, the agency's position is now that treating common, mild symptoms associated with normal life stages or processes as "diseases" is not consistent with the intent of DSHEA.⁷ As a caveat, however, the FDA will treat a claim as a disease claim if a claim asserts that a product has an effect on an abnormal condition associated with a natural state if the abnormal condition is uncommon or can cause significant or permanent harm.

Permissible	Impermissible	Examples of Age Related Stage of Life Functions ⁸
X		Mild mood changes, cramps, and edema associated with the menstrual cycle
X		Hot Flashes
X		Wrinkles associated with aging
X		Other signs of aging on the skin (e.g., liver spots, spider veins)
X		Presbyopia (inability to change focus from near to far and vice-versa)
X		Mild memory problems associated with aging
X		Hair loss associated with aging
X		Noncystic acne.
	X	Toxemia of pregnancy
	X	Hyperemesis gravidarum
	X	Acute psychosis of pregnancy
	X	Osteoporosis
	X	Alzheimer's disease and other senile dementias
	X	Glaucoma
	X	Arteriosclerotic diseases of coronary, cerebral or peripheral blood vessels
	X	Cystic acne
	X	Severe depression associated with the menstrual cycle.

Note that in the examples given by FDA in the rule, the agency initially stated that "Morning sickness associated with pregnancy" and "leg edema associated with pregnancy" were permissible structure/function claims. **On February 9th the agency issued a statement that it is reconsidering its position on structure/function claims relating to pregnancy and advised marketers not to make any such claims until it has completely considered the issue.**

Permissible Stage of Life Claims ⁹	Comment
Supports a normal healthy attitude during PMS	PMS is generally a common, mild condition that is associated with a normal physiologic process rather than a disease.
Supportive for menopausal women	Claim is acceptable because it is a general statement that does not refer to symptoms of any conditions at all.
Diminish the normal symptomology of PMS or Menopause	Acceptable so long as they do not suggest prevention or treatment of a disease such as osteoporosis or other disease associated with these states.

Impermissible Natural State Related Claims ¹⁰	Comment
Helps to maintain normal urine flow in men over 50 years old.	This is an implied disease claim because the "normal" state in men over 50 is diminishing urine flow, which is in most cases due to BPH, so the apparent "maintenance" is really an improvement claim. "Improvement" claims imply treatment.

iv. Represented Effect on a Disease - General Considerations

The rule recognizes that there are many ways to make a disease claim without expressly stating the name of the disease. Consequently, there are five listed methods that the FDA will evaluate to determine if a marketer intends to imply a disease claim. These include:

- The name of a product implies a disease;
- Representing the product contains an ingredient that has been regulated as a drug and is well known to consumers for its use in preventing or treating a disease;
- Citation to a publication or reference, *if* the citation refers to a disease use, *and* if, in the context of the labeling, the citation implies treatment or prevention of a disease;
- Use of the term "disease" or "diseased" except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient;
- Use of pictures, vignettes, symbols, or other graphic material to reference a disease.

Permissible Claims ¹¹	Comment
Names that include the name of an organ; e.g., "Heartabs"	This is appropriate if the product is "to maintain healthy circulation or some other role related to the structure or function of the heart that does not imply treatment or prevention of a disease.
Naming a product "Soothing Sleep"	This would be appropriate if the labeling made clear that the product was intended only for occasional sleeplessness, and not for insomnia treatment.
Naming a Product "HeptaCare" or "Heptahealth"	These names could be used <i>if</i> the labeling made clear that the product was intended for general liver health and not intended to prevent or treat hepatitis.
Use of the word "Prescription" or the "Rx" symbol in a product name or labeling	These will not normally be considered implied disease claims unless they are used in a manner that misleads consumers into believing they are purchasing a prescription drug without a prescription.
Referencing the title of an article that identifies a specific disease in advertising material .	This is not a disease claim so long as there is not undue emphasis or prominence on the reference to the article, such as highlighting the article, bolding it, placing it in large font, etc. In addition, the citation must be to a bona fide article. FDA also <i>encourages</i> marketers to cite references that provide a balanced discussion of the evidence supporting a structure/function claim. As always, the context must be considered. If the overall context is to imply a disease prevention or treatment, it will not be permissible.

Impermissible Claims ¹²	Comment
Use of the heart symbol	Use of the heart symbol has become widely associated with prevention of heart disease.
Naming a product "CarpalHealth"	The names contain the name, or a recognizable portion of the name, of a disease.
Naming a product "CircuCure"	The name implies curative, preventative, or treatment properties.
Referencing the title of an article that identifies a specific disease in a product label or packaging .	The FDA views references to articles that are placed directly on a product label in a different light from the same reference in advertising material.

- v. *A Claim that a Product Belongs to a Class of Products that is Intended to diagnose, Mitigate, Treat, Cure or Prevent a Disease*

Some product class names are so strongly associated with disease treatment or prevention that claiming membership in the product class implies that the product will treat or prevent the disease. Again, however, the FDA will focus on the intended use of the product in making the ultimate determination whether a claim will constitute a disease claim.

Permissible Product Class Claims ¹³	Comment
Laxative Claims	Laxative claims are appropriate if the claim is qualified to make it clear the product is intended only for occasional irregularity. Claims to treat chronic constipation are disease claims.
Appetite Suppressant Claims	Being overweight is not a disease, so an appetite suppressant claims may be intended for ordinary weight loss rather than to treat obesity.
Tonic Claims	A tonic is generally anything that refreshes, and therefore does not constitute a disease claim.
Antispasmodic Claims	An antispasmodic is not closely associated with treatment or prevention of gastrointestinal disease.

Impermissible Product Class Claims ¹⁴	Comment
Antibiotic Claims	Antibiotics are a commonly recognized class of prescription drugs.
Analgesic Claims	Analgesics are a commonly recognized class of OTC drugs.
Anti-obesity Claims	While appetite suppressant claims are appropriate for simple weight loss, obesity is a disease. Consequently, an anti-obesity claim will constitute a disease treatment claim.
Anti-inflammatory	Inflammation claims are closely associated with serious gastrointestinal diseases and other disorders.
General Disease Prevention Claims	A general statement that a product prevents the onset of disease is a broad-based prevention claim and is impermissible.

vi. Substitute for Disease Therapy

The FDA's position is that claiming a dietary supplement is a substitute for a specific drug or therapy is a means of communicating that a product is intended to treat a disease that the drug would otherwise treat.

Impermissible Drug Substitute Claims	Comment
Herbal Prozac	Claiming a supplement (e.g., St. John's Wort) is a replacement for Prozac is a claim that it will treat depression.
Herbal Viagra	This amounts to a claim that a product will treat erectile dysfunction.

vii. *Augmentation of Therapy or Drug for Disease*

If a marketer claims that a supplement will augment or assist a drug action, the FDA will consider the claim to be a disease claim.

Permissible Drug Therapy Augmentation Claims ¹⁵	Comment
Use as part of your diet to help maintain a healthy blood sugar level.	Since there is no reference to the drug insulin, there is not implication that the supplement is used to augment the insulin to treat diabetes.

Impermissible Drug Therapy Augmentation Claims ¹⁶	Comment
Use as part of your diet when taking insulin to help maintain a healthy blood sugar level.	The reference to insulin implies that the supplement is intended to assist in the treatment of diabetes.

viii. *Role in Body's Response to Disease or Disease Vector*

A "vector of disease" is an organism or object that is able to transport or transmit an agent, such as a virus or bacterium, that is capable of causing disease in man.¹⁷ If a claim represents that a supplement plays a role in response to a specific disease or disease vector, it is evidence that the marketer intends to position the product as a disease prevention or treatment product.

Permissible Bodily Response Claims ¹⁸	Comment
Supports the immune system.	This claim is a general reference to an effect on a body system. It does not identify any specific pathogen or vector of disease, and therefore does not imply prevention or treatment of a disease state.

Impermissible Bodily Response Claims ¹⁹	Comment
Supports the body's antiviral capabilities.	This claim represents that a product will treat or prevent a specific class of diseases (<i>i.e.</i> , those caused by viruses, such as colds, hepatitis, & HIV).
Assists the body's ability to resist infection.	This claim represents that a product will treat or prevent a specific class of diseases (<i>i.e.</i> , infections).

ix. Treatment or Prevention of Adverse Effects Associated with a Disease Therapy

If a product claims to treat or prevent adverse effects associated with a disease therapy, the claim will be treated as a disease treatment claim *if* the adverse effect itself constitutes a disease. Consequently, a claim that a supplement is useful because it counterbalances the effects of a drug in depleting a nutrient or interfering with the metabolism of a nutrient is acceptable as a structure/function claims because it does not suggest treatment of an adverse reaction that meets the definition of a disease. Bear in mind, however, that this can be a close call because if the claim suggests that a supplement is intended to augment a specific drug or therapy for a disease, or serve as a replacement for a drug, then the statement will be viewed as a disease claim.²⁰

Permissible Adverse Event Claims²¹	Comment
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Helps maintain healthy intestinal flora.	This is a general health maintenance claim that does not imply an effect on a disease.
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Impermissible Adverse Event Claims²²	Comment
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Reduces nausea associated with chemotherapy	Nausea is recognized as a disease state, and chemotherapy patients commonly become nauseated. The claim is therefore an implied disease treatment claim.
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To aid persons with reduced immune function, such as chemotherapy patients.	See above comment.
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Helps persons on antibiotics maintain healthy intestinal flora.	Persons on certain antibiotics are at risk of developing overgrowth in the gut of a pathogenic organism because antibiotics can suppress normal intestinal flora that act to prevent infection in the intestinal tract. Consequently, an implied infection disease claim exists.
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x. Otherwise Suggests an Effect on a Disease or Diseases

Okay, here comes the inevitable catchall! If a claim "otherwise suggests an effect on a disease or diseases" it will be evidence that the marketer intends to position the product as a disease treatment or preventative. Consequently, the only meaningful guidance given by FDA on this point is a number of examples presented in the regulation. Also, bear in mind that many of the claims identified below as permissible structure/function claims are derived from FDA monographs for over the counter drug products. The FDA has acknowledged that supplements may use statements included in monographs so long as the claim does not violate the rules set forth above. In addition, if a supplement contains an ingredient covered by an OTC monograph, the supplement marketer must include all information that is material in light of consequences that may result from use of the product or representations made about it. For example, if an OTC monograph requires a label statement that products containing a particular ingredient should not be used by persons taking a prescription MAO inhibitor, the supplement must also make that disclosure on its label.²³

Permissible Claims ²⁴	Comment
Provides nutritional support for women during premenstruation by promoting proper fluid balances and breast health.	This structure/function claim addresses a natural state, and is therefore not a disease claim.
Ginger supports the cardiovascular system by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation.	Isn't it great the way FDA provides such superb consumer friendly examples that clearly every marketer would like to take advantage of?
Minor pain relief claims such as for muscle pain following exercise.	A claim that a product is intended to treat minor pain without reference to any other conditions, symptoms, or parts of the body that would imply disease treatment or prevention is an appropriate structure/function claim because minor pain, by itself, can be caused by many conditions, not all of them disease related.
Boosts stamina	
Helps increase muscle size	While this can be an appropriate structure/function claim, it can also subject the product to regulation as an anabolic steroid under the controlled Substances Act.
Helps enhance muscle tone	
"Smoking alternative," or "temporarily reduces your desire to smoke"	The claim does not imply treatment of nicotine addiction or relief of nicotine withdrawal symptoms, or prevention or mitigation of tobacco related illnesses.
Relief of "sour stomach" or "upset stomach"	These are acceptable claims because they refer to a nonspecific group of conditions that have a variety of causes, many of which are not disease related.
"Relief of occasional heartburn"	Occasional heartburn and occasional acid indigestion can be considered nonspecific symptoms resulting from overindulgence or other sporadic situations.
Antiflatulence claims "Alleviates symptoms referred to as gas" "Alleviates bloating" "Alleviates pressure" "Alleviates fullness" "Alleviates stuffed feeling"	These claims are derived from the antiflatulence monograph and are acceptable structure/function claims because the symptoms in the claims are not sufficiently characteristic of specific diseases.
"For the prevention and treatment of the nausea and vomiting or dizziness associated with motion"	This claim comes from the FDA's antiemetics monograph and is not associated with a permanent or serious disease.
"For the relief of occasional sleeplessness"	From the FDA's nighttime sleep-aids monograph. This is acceptable because occasional sleeplessness is not a characteristic symptom of a disease.

Permissible Claims	Comment
<p>"Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness" and other claims from the stimulants (alertness aids) monograph.</p>	<p>Occasional fatigue and drowsiness are not characteristic symptoms of a specific disease or class of diseases. Claims must be careful not to imply treatment of chronic fatigue syndrome or narcolepsy.</p>
<p>Claims from the daytime sedatives monograph are usually acceptable. "For occasional simple nervous tension" For nervousness due to common every day overwork and fatigue" "Promotes a relaxed feeling" "Calming and relaxing" "Gently soothe away tension" "Calmative" "Resolving that irritability that ruins your day" "Helps you work relaxed"</p>	<p>All of these claims suggest occasional rather than long-term or chronic mood changes. Although occasional or acute symptoms can be characteristic of diseases in other settings, none of the occasional symptoms referred to is characteristic of a specific disease.</p>
<p>"Arouses or increases sexual desire and improves sexual performance"</p>	<p>This claim is acceptable because it does not imply treatment of a disease.</p>
<p>"Digestive aid"</p>	<p>This statement by itself, is an acceptable structure/function claims if the labeling does not otherwise imply treatment or prevention of a disease. It does not mention a characteristic symptom or sign of a disease.</p>
<p>"Stool softener"</p>	<p>Same as above.</p>
<p>"Weight control"</p>	<p>Same as above.</p>
<p>"Menstrual"</p>	<p>Same as above.</p>
<p>"Laxative"</p>	<p>This is not a disease claim so long as the labeling makes it clear that the intended use is for treatment of occasional rather than chronic constipation.</p>

Impermissible Claims ²⁵	Comment
Antimicrobial, antiseptic, kills germs ²⁶	These claims refer to disease vectors.
Stating "Hormones" are present in product ²⁷	Hormones are classified as drugs.
Use of term "sunscreen" in product even if product is not promoted for skin cancer prevention ²⁸	Sunscreens are drug products.
Alcohol intoxication & drug addiction ²⁹	Deemed "transient" diseases even though self induced.
Naming a product "Pain-Free" or identifying it as a "pain product" in conjunction with a product intended for joint support	This implies treatment of symptoms associated with arthritis.
Deters bacteria from adhering to the wall of the bladder and urinary tract.	Claim implies prevention of bacterial infections of the bladder and urinary tract.
Dietary support during the cold and flu season.	Claim implies that the product will prevent colds and flu or mitigate the symptoms.
"Use as part of your smoking cessation plan"	Smoking cessation claims are disease claims because it implies the product is useful in treating nicotine addiction.
"Relief of recurrent acid indigestion," or "Relief of persistent heartburn"	These are indicia of significant illness and therefore are disease claims.
"Relief of indigestion" "Relief of heartburn"	These need to be qualified by inserting the term "occasional" before the ailment.
"Helps you fall asleep if you have difficulty falling asleep" "Helps to reduce difficulty falling asleep"	These are disease claims unless the context makes clear that the product is only for occasional sleeplessness. Otherwise, they imply treatment of insomnia.
"Helps treat chronic fatigue or daytime drowsiness"	These claims can be symptoms of chronic fatigue syndrome and narcolepsy, respectively.
"For nervous tension headache"	"Tension headache" meets the definition of a disease.
"Helps restore sexual vigor, potency, and performance" "Improves performance, staying power, and sexual potency" "Builds virility and sexual potency"	These are disease claims because they use the term "potency," which implies treatment of impotence, which is a disease. However, if these claims make it clear that they are intended solely for decreased sexual function associated with aging they could be acceptable structure/function claims.

Impermissible Claims	Comment
"For the relief of symptoms of benign prostatic hypertrophy" "To relieve urinary urgency and frequency, excessive urinating at night, and delayed urination"	These are disease claims because benign prostatic hypertrophy meets the definition of a disease.
"Relieves excessive secretions of the nose and eyes"	These are characteristic symptoms or signs of hay fever, which qualifies as a disease.
"Nasal decongestant"	This indicates that it is for the treatment of characteristic symptoms of colds, flu, and hay fever.
"Expectorant"	This indicates that it is for the treatment of characteristic symptoms of colds, flu, and bronchitis.
"Bronchodilator"	Indicates that it is for treatment of bronchospasm, which is a characteristic symptom of asthma.
"For treatment of nocturnal leg cramps"	Nocturnal leg cramps, which are a condition of localized pain usually occurring in middle life and beyond with no regular pattern concerning time or severity because nocturnal leg cramps do not meet the definition of disease.

What Has Not Changed

The new rule presents dramatic changes from the proposed rule, but only in terms of defining a "disease" and the scope of permissible structure/function claims. Bear in mind however, that the FDA disclaimer and 30 day notice provisions still apply. That is, if you use a structure/function claim in your labeling, you must place an asterisk or other appropriate mark by your structure/function claims which references the following disclaimer:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Similarly, you must submit a written certification to the FDA that you have adequate substantiation for the claim. This certification must be filed within 30 days after first marketing the supplement with the claim.

So there you have it! The rule is still not the picture of clarity, but regardless of the lack of precision (and I do not believe absolute precision is possible), it is clearly more permissive than the proposed rule. While the fly-by-night operators will continue to claim their supplements will cure cancer, heart disease, AIDS, and every other disease under the sun, ethical marketers have much greater latitude than they have ever had.

1. 65 Fed. Reg. 1013.
2. 65 Fed. Reg. 1015.
3. 65 Fed. Reg. 1016.
4. 65 Fed. Reg. 1016 - 17.
5. 65 Fed. Reg. 1018.
6. 64 Fed. Reg. 1018.
7. 65 Fed. Reg. 1020.
8. *Id.*
9. 65 Fed. Reg. 1021.
10. *Id.*
11. 65 Fed. Reg. 1024.
12. *Id.*
13. 65 Fed. Reg. 1026
14. *Id.*
15. 65 Fed. Reg. 1028
16. *Id.*
17. 65 Fed. Reg. 1028.
18. 65 Fed. Reg. 1028 - 29.
19. 65 Fed. Reg. 1029.
20. 65 Fed. Reg. 1029.
21. *Id.*
22. *Id.*
23. 65 Fed. Reg. 1031.
24. 65 Fed. Reg. 1029 - 31.
25. Unless otherwise indicated, all claims are derived from 65 Fed. Reg. 1029 - 31.
26. 65 Fed. Reg. 1014.
27. *Id.*
28. *Id.*
29. 65 Fed. Reg. 1015.