# Legal & Ethical Responsibilities for Retail Salespeople Selling Dietary Supplements

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# Introduction

If you work with dietary supplements in a clinical or retail setting, no doubt clients or customers ask you for recommendations about which dietary supplements might be helpful for a specific situation. Naturally you will want to provide appropriate responses when these occasions arise, but you are faced with two ethical challenges: making evidence-based recommendations that are also legal recommendations. This document will explore how to properly go about doing just that. But first, let's start with some regulatory background.

# Regulatory Background

Despite what some people think, the dietary supplement industry is highly regulated. Following is a brief overview of the different industry laws/regulations. As you review them, keep in mind that there are only a few of these that directly impact you, regarding your interactions with customers, as indicated.

## Food, Drug, and Cosmetic Act of 1938 (FD&C)

FD&C is a set of laws passed by Congress in 1938 giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics. This includes the definition of foods, and issues surrounding food adulteration and claims associated with foods. With the passage of the Nutrition Labeling and Education Act of 1990, and the subsequent passage of Dietary Supplement Health and Education Act of 1994 (both discussed below), FD&C was amended to more specifically address and regulate dietary supplements.

## Nutrition Labeling and Education Act of 1990 (NLEA)

The law gives the FDA authority to require nutrition labeling of most foods regulated by the Agency; and to require that all nutrient content claims (for example, 'high fiber,' 'low fat,' etc.) meet FDA regulations. It also established a select group of authorized Health Claims characterizing the relationship of any substance (e.g., a specific food or component of food) to a disease or health-related condition, and the conditions under which the Health Claim could be made. In most cases these claims are not applicable to dietary supplements, although there are a select few which may qualify, such as the claim defining the relationship between calcium and osteoporosis. Health claims will be further discussed later in this document.

## Dietary Supplement Health and Education Act of 1994 (DSHEA)

This is a statute of United States Federal legislation which defines and regulates dietary supplements. Under the act, supplements are effectively regulated by the FDA for Good Manufacturing Practices under 21 CFR Part 111 (see the following discussion about this). DSHEA spells out regulations regarding the manufacture and sale of dietary supplements, and defines a dietary supplement as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient noted in clause (A), (B), (C), (D), or (E)."

Further, this may include individual or combination vitamin and mineral supplements, herbal supplements, certain limited types of hormones (e.g., melatonin, DHEA), certain biological substances (e.g., glucosamine sulfate, chondroitin sulfate), and specialty products containing any combination of these ingredients. The products might be formulated for a variety of intended purposes, including but not limited to promoting energy metabolism, reducing the effects of stress, alternative and complementary health therapies, promoting weight loss and providing sports nutrition benefits.

The act defines permissible labeling claims, including structure/function claims, and outlines safety requirements for new dietary ingredients. Structure/function claims will be further discussed later in this document.

## The Food and Drug Administration Modernization Act of 1997 (FDAMA)

FDAMA amended the FD&C relating to the regulation of food, drugs, devices, and biological products. With the passage of FDAMA, Congress enhanced FDA's mission in ways that recognized the Agency would be operating in a 21st century characterized by increasing technological, trade and public health complexities. Relevant to the dietary supplement industry, FDAMA provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences. From a practical standpoint, this generally doesn't happen.

## Current Good Manufacturing Practices (cGMPs)

These regulations stipulate current good manufacturing practices for dietary supplements, requiring that proper controls are in place for dietary supplements so that they are processed in a consistent manner to meet identity, purity, strength, and composition quality standards. cGMPs apply to all domestic and foreign companies that manufacture, package, label or hold dietary supplements, including those involved with the activities of testing, quality control, packaging and labeling, and distributing them in the U.S. All supplement companies are required to maintain cGMPs, and to have a program in place to audit all contract manufacturing, packaging and distribution facilities that they use, to verify compliance with cGMPs.

## Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act)

The Bioterrorism Act directs the Food and Drug Administration (FDA) to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply (including dietary supplements) and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that food facilities register with FDA, and FDA be given advance notice on shipments of imported food. Registration pertains only to facilities that manufacture/process, pack, or hold food, as defined in 21 CFR 1.227, for consumption by humans or animals in the U.S.

## Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

This act addresses, among other issues, the labeling of foods (including dietary supplements) that contain certain food allergens. Under FALCPA, a "major food allergen" is an ingredient that is one of the following five foods or from one of the following three food groups or is an ingredient that contains protein derived from one of the following: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts or soybeans.

## Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006

This Act requires compliance with the adverse event reporting and recordkeeping requirements prescribed for dietary supplement manufacturers, packers, and distributors.

## Food Safety Modernization Act of 2011 (FSMA)

FSMA was enacted to prevent widespread occurrences of foodborne illness. FSMA includes a requirement that companies manufacturing, processing, packing or holding human food identify food -safety hazards and implement preventive controls. This may include manufacturers of dietary supplements.

**Nutraceutical**

**The term nutraceutical was coined in the 1990s by Dr. Stephen DeFelice, who defined it as "any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease." Health Canada defines nutraceutical as "a product isolated or purified from foods, and generally sold in medicinal forms not usually associated with food and demonstrated to have a physiological benefit or provide protection against chronic disease." So essentially, a nutraceutical could include vitamins, minerals, herbs, and a variety of other substances.**

# Evidence-Based Recommendations

For the first decade or so of my almost 40 years in the natural product industry, I was in retail—and I can remember the very first time I knew that this was the business I wanted to be in for the rest of my life. A customer entered the store and walked right up to me with a big smile on her face. She said, "You changed my life." During a previous visit I recommended that she take L-tryptophan to help her get to sleep at night (this was before melatonin was available). Apparently, it made all the difference in the world for her and she was finally able to get a good night's sleep. The high I experienced from that moment changed my life. I wanted to keep helping people and feeling that same high repeatedly.

## It works/it doesn't work

As retailers, no doubt most of you have had a similar experience with customers telling you that your recommendation made a significant difference for them. Not only is it a great feeling, but it's good for business. Delighted customers are likely to be long-term customers, and they're also likely to buy other products you recommend for them since you've gained their trust with previous credible recommendations. Everyone is happy—it's a win-win. Except that it doesn't always work that way.

Because of biochemical individuality, no single nutraceutical or product is going to work the same for everybody. That is a given and is to be expected. What is distressing, however, is when you sell a product to customers and all or most of them don't seem to experience any benefits. Hearing "This product doesn't work," is incredibly disappointing and is not good for business. Also, it doesn't help your credibility. So, the big question is what can be done to help improve the chances of hearing customers sing your praises for making the right recommendations?

While there is no answer to this question that will assure success 100% of the time, there are some key things you can and should be doing to help improve chances for keeping your customers happy with the products you recommend (and keeping your accountant happy as well). First and foremost is to critically evaluate all the dietary supplements you are considering bringing into your store.

## Evaluating dietary supplements

In my opinion, to properly evaluate the potential efficacy of a dietary supplement there are a few questions you should be asking before placing an order. These questions include:

1. Is there human clinical research on the nutraceuticals?
2. Is the type and amount of the nutraceutical consistent with the research?
3. Is one bottle enough for consumers to experience results?
4. Should I rely on my own personal experience for evaluating a supplement/nutraceutical?
5. Do I trust the company?

In addition, you will probably need to ask the sales rep or broker for documentation to help you answer these questions (at least the first two) and properly evaluate the new dietary supplements. Following is a discussion of these questions along with the documentation you may need.

## Is there human clinical research on the nutraceuticals?

When a sales rep introduces you to an interesting new product with compelling claims, take a close look at the nutraceuticals the product provides. Many different nutraceuticals may be marketed for a given benefit. That doesn't mean, however, that all those nutraceuticals have actually been studied in human clinical research for that specific benefit. The emphasis here is on human clinical research. Animal research does not necessarily translate to human beings; and in-vitro research (i.e. cell lines in a petri dish), while valuable for understanding mechanism

of action, is definitely not directly translatable. Furthermore, testimonials, surveys or even a doctor's clinical experience in his/her practice does not take the place of real human clinical research.

Request literature from the sales rep that explains the human research conducted on the nutraceuticals in question. If you are a person with a science background, you might like to see copies of the actual studies. In most cases, however, a document that provides summaries of the research will give you sufficient data on which to base a decision. Third-party literature that explains the research is particularly helpful since it can also serve as a sales tool with customers.

## Is the type and amount of the nutraceutical consistent with the research?

Assuming that the dietary supplement does contain a nutraceutical with demonstrated efficacy, it is important to consider if it is the correct type and amount of that nutraceutical. For example, it is all well and good for a manufacturer to put black cohosh in a menopause formula, but for it to have clinical relevance based upon published research, the black cohosh needs to be a root extract standardized for 2.5% triterpene glycosides and present in a daily amount of 40-80 mg. There is no scientific evidence to suggest that a different extract of black cohosh, or even just plain black cohosh root powder, will have the same beneficial effect for menopausal symptoms—especially when provided in amounts inconsistent with the research. The bottom line is that it is not enough to include some amount of a popular nutraceutical in a supplement. It must be the right form of the nutraceutical and present in clinically relevant amounts (based on human clinical research).

Sometimes dietary supplements contain proprietary blends of nutraceuticals without specific information on the amount of each nutraceutical present. In this instance, you should determine if there are any claims based upon a nutraceutical in the proprietary blend. If there are no claims based upon the proprietary blend (i.e., it is just window dressing), then there is no problem. If, on the other hand, claims are based upon one of the nutraceuticals in the proprietary blend, it will be difficult, if not impossible, to ascertain whether the product actually provides the amount of specific nutraceuticals that is consistent with the research. If you are not able to obtain the necessary information, you may want to carefully consider if this is a product you want to stock on your shelves.

If you know the amounts of the relevant nutraceuticals in the formula, the same literature request that you make of the sales rep in association with the previous question should also provide the information you need to help answer this question. In the instance of proprietary blends, you will likely wish to ask the rep if any of the claims are based upon nutraceuticals in the blend.

## Is one bottle enough for consumers to experience results?

The answer to this question will not necessarily provide you with the information you need to decide about carrying the product in the first instance, but rather will help you in assessing the product's efficacy and responding to customer concerns.

While some products like melatonin or caffeine provide a fairly rapid response, others take longer to assess a discernible benefit. In fact, some products may require supplementation for more than 30 days, so if a customer uses a standard bottle it will likely not be sufficient to show results. For example, most human studies using glucosamine were conducted for at least six weeks, and some as long as six months. Therefore, daily use of glucosamine for one month is not long enough to experience benefits. To provide customers with realistic expectations, you should let them know how long it may take before they notice a difference. Consequently, they may want to purchase a larger size bottle or two smaller bottles so that they give the product a fair chance. This will reduce the potential product returns and customer contention that the product is ineffective.

The same literature request that you make in association with the first question should provide the information you need to help answer this question as well. If not, ask the sales rep about the length of the study(ies) so that you are able to advise customers accordingly.

### Should I rely on my own personal experience for evaluating a supplement/ nutraceutical?

Often, we have a tendency to sell products to customers based upon our own personal experience with those products. When a product has worked well for us, the personal testimonial does tend to have a positive impact as part of your sales presentation to customers. The problem with this approach is when a given product does not work for you. In this instance, it is important to remember what was stated earlier: biochemical individuality dictates that no single nutraceutical or product is going to work the same for everybody. Consequently, even if a given product does not work well for you, that does not mean it won't work well for a customer. Stated simply, sell to the customer, not to yourself. Rely on what the research shows, not your own personal experience.

### Do I trust the company?

It is important to consider the basis upon which the company formulates products. Ideally, formulations should be based upon real science, not "marketing science" or personal philosophy. To be clear, while I have nothing against personal philosophy it should not serve as the basis for product formulations without accompanying scientific support. For example, it may be a company's philosophy that all their herbal products should only provide whole herb powders or crude extracts, not standardized extracts. However, if their ginkgo biloba leaf product is a crude extract, this is problematic for two reasons. First, only standardized ginkgo leaf extracts (e.g., 24% flavone glycosides, 6% terpene lactones) have been researched in humans and found to offer cognitive benefits. Second, some crude extracts from ginkgo leaves contain the constituent ginkgolic acid. This constituent can have strong allergenic properties and might have possible mutagenic and carcinogenic properties. Standardized ginkgo leaf extract contains no greater than 5 ppm in concentration of ginkgolic acids, making it both safe and effective.

It is also important to consider the company's past track record and whether you have had previous negative experiences with various products offered by that company. While a single, isolated negative experience with a product may not mean anything, repeated negative experiences should be a red flag.

# Legal Recommendations

In addition to making sure your recommendations are evidence-based, they must also be legal. By this I mean that individuals engaged in the practice of recommending and/or selling dietary supplements must be careful to avoid making claims that a dietary supplement can be used to treat an illness. This is the legal definition of a drug. Any statements to this effect will cause the supplement that you're recommending being considered an unapproved drug by the FDA. Following are some guidelines to help you keep your recommendations legal.

### Avoid Diagnosing

Only licensed physicians can diagnose. You should avoid doing so. Now you may not think that this is a problem, but you'd be surprised how easily you can accidentally become involved in a diagnosis. For example, you might say, "With your low energy levels and headaches, it sounds like you have hypoglycemia. I recommend that you take Chromium Picolinate and use small protein drinks throughout the day." Without realizing it, you've just diagnosed your customer as having hypoglycemia, a medical condition. If, on the other hand, you were to talk about maintaining healthy blood sugar levels, this would not be diagnosing. For example, "With your low energy levels and headaches, it is important to maintain healthy blood sugar levels. The use of Chromium Picolinate and small protein drinks throughout the day may help you do that. At the same time, you may wish to see your doctor and ask about a glucose tolerance test, just in case you have a blood sugar problem such as hypoglycemia."

### Avoid Prescribing

Only licensed physicians and pharmacists can prescribe. This is the area where you can really make a mistake if you're not careful, because there is a fine line between recommending and prescribing. For example, you shouldn't say to your customer, "This product contains glucosamine sulfate which may help to reduce your

arthritis pain." In this case, you would have just prescribed an unapproved drug for arthritis. You can, however, say, "This product contains glucosamine sulfate which provides you with support for the repair and maintenance of healthy joints." Remember, if a customer backs you into a corner and wants you to make an illegal claim, there's no reason you shouldn't respond, "I can't legally say that."

Essentially, there are three types of claims which may be made in association with a dietary supplement: 1) Health Claims, 2) Qualified Health Claims, and 3) Structure & Function Claims—the primary type of claim you'll be using in your discussions with customers. Often, there is some confusion about what constitutes one or the other.

## Health Claims

For clarification purposes, under the 1990 Nutrition Labeling and Education Act, the FDA has approved health claims relating to:

- Calcium, Vitamin D, and Osteoporosis
- Dietary Lipids (Fat) and Cancer
- Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease
- Dietary Non-Carcinogenic Carbohydrate Sweeteners and Dental Caries
- Fiber-containing Grain Products, Fruits and Vegetables and Cancer
- Folic Acid and Neural Tube Defects
- Fruits and Vegetables and Cancer
- Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble fiber, and Ri sk of Coronary Heart Disease
- Sodium and Hypertension
- Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease
- Soy Protein and Risk of Coronary Heart Disease
- Stanols/Sterols and Risk of Coronary Heart Disease

Please note that there are only a few health claims associated with dietary supplements. This includes the calcium and vitamin D claims, the folic acid claim, the soy protein claim (assuming that we are talking about actual soy protein, and not just soy isoflavone tablets), and the plant sterol/stanol claim. In any case, no other health claims other than those approved by NLEA can be made, even if research supports it. Here is the full-text for each of the health claims related to dietary supplements:

- Calcium and osteoporosis health claim:
  - "Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis" or
  - "Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life."
- Calcium, vitamin D, and osteoporosis:
  - "Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis" or
  - "Adequate calcium and vitamin D throughout life, along with physical activity, may reduce the risk of osteoporosis in later life."

- Folate and neural tube defects claim:
    - "Healthful diets with adequate folate (or folic acid) may reduce a woman's risk of having a child with a brain or spinal cord defect."
- Soy protein and risk of coronary heart disease claim:
    - "25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of soy protein." or
    - "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides __ grams of soy protein."
- Plant sterol/stanol esters and risk of coronary heart disease claim:
    - "Foods containing at least 0.65 grams per of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [ name of food] supplies __ grams of vegetable oil sterol esters."
    - "Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of plant stanol esters."

## Qualified Health Claims

Qualified health claims are considered by the FDA to be supported by less scientific evidence than an authorized health claim. FDA requires that qualified claims be accompanied by a disclaimer that explains the level of the scientific evidence supporting the relationship. Following are the specific qualified health claims related to dietary supplements:

- Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps:
    - Claim Statement for Colon/Rectal Cancer: "Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer, however, FDA has determined that this evidence is limited and not conclusive."
    - Claim Statement for Recurrent Colon Polyps: "Very limited and preliminary evidence suggests that calcium supplements may reduce the risk of colon/rectal polyps. FDA concludes that there is little scientific evidence to support this claim."
    - Must provide at least 200 mg calcium per serving.
- Selenium & Cancer:
    - "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." or,
    - "Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive."
    - Requires at least 14 mcg selenium per serving, but not to exceed 400 mcg/day.
- Antioxidant Vitamins & Cancer:
    - "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive." or,

    - "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive." or,
    - "FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive."
    - Requires at least 12 mg vitamin C and 6 IU vitamin E per serving.
    - May not exceed 2000 mg vitamin C and/or 1000 mg vitamin E per day.
- Green Tea & Cancer:
    - "Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence for this claim." or,
    - "Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim."
- Omega-3 Fatty Acids & Coronary Heart Disease:
    - "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of the food] provides __ grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]"
    - May not exceed 2 grams of EPA and DHA daily.
    - Must meet the criterion for low saturated fat regarding the saturated fat content (≤ 1 g per reference amount customarily consumed).
- B Vitamins & Vascular Disease:
    - "As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive."
    - Products that contain more than 100 percent of the Daily Value (DV) of folic acid (400 micrograms) must identify the safe upper limit of daily intake with respect to the DV. The folic acid safe upper limit of daily intake value of 1,000 micrograms (1 mg) may be included in parentheses.
- Phosphatidylserine & Cognitive Dysfunction and Dementia:
    - "Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim." or,
    - "Consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence supporting this claim."
    - The soy-derived phosphatidylserine must be of very high purity.
- Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia:
    - "Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that the evidence is inconsistent and not conclusive." or,

    - "Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension."

- 0.8 mg Folic Acid & Neural Tube Birth Defects:
    - "0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects. "
    - There is a health claim for folic acid and neural tube birth defects.
- Psyllium Husk & Diabetes:
    - "Psyllium husk may reduce the risk of type 2 diabetes, although the FDA has concluded that there is very little scientific evidence for this claim." or,
    - "Psyllium husk may reduce the risk of type 2 diabetes.  FDA has concluded that there is very little scientific evidence for this claim."
- Chromium Picolinate & Diabetes:
    - "One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."

## Structure & Function claims

Structure & Function (S&F) claims are not health claims or qualified health claims.  They are claims made about the role of a nutrient, herb or other dietary supplement ingredient with regard to a structure or function in the human body.  The Dietary Supplement Health & Education Act (DSHEA) of 1994 allows S&F claims in association with dietary supplement products.  S&F claims must have research to support them.

The types of S&F claims are as follows:

- A statement that claims a benefit related to a classical nutrient deficiency disease and that discloses the prevalence of such disease in the U.S.;
- A statement that describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, or characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function; or
- A statement that describes the general well-being from consumption of a nutrient or dietary ingredient.
- May include natural life processes (e.g., menopause)

Examples of S&F claims include:

- This product contains calcium, which gives nutritional support for building and maintaining bone density.
- This product contains vitamin C, which gives nutritional support for immune response.
- This product contains herbs that may provide support for joint comfort and flexibility.
- This product contains creatine, which may help you achieve greater muscle growth.

Following is a table which provides a more extensive understanding of the FDA's position on permitted and prohibited structure/function claims.

## Summary of FDA Position on Structure/Function Claims

Adapted from Dietary Supplements and Functional Foods: A Practical Guide to FDA Regulation (2001, Thompson Publishing Group)

| Type of Structure/ Function Claim | Permitted or Prohibited Claim | |
|---|---|---|
| **Adverse Events** | **Permitted** | Claims that a product may be useful in counterbalancing the effects of a drug in depleting a nutrient or interfering with the metabolism of a nutrient |
| | **Prohibited** | Claims suggesting that the supplement is intended to augment a specific drug, drug action or therapy for disease.<br>E.g., helps individuals using antibiotics to maintain intestinal flora (implies that using while taking antibiotics will prevent or mitigate a disease) |
| **Aging** | **Permitted** | Claims regarding the signs of aging, which is considered a natural state, including: Signs of aging on the skin;<br>E.g., wrinkles, liver spots, spider veins, presbyopia (inability to change focus from near to far and vice versa) associated with aging, hair loss associated with aging, mild memory problems associated with aging |
| | **Prohibited** | Alzheimer's disease and other senile dementia |
| **Acne** | **Permitted** | Noncystic acne |
| | **Prohibited** | Cystic acne |
| **Cancer** | **Permitted** | |
| | **Prohibited** | Cancer protection/prevention:<br>E.g., protective against the development of cancer<br>E.g., maintain a tumor-free state<br>E.g., prevention of cancer metastases; prevents the spread of neoplastic cells |
| **Cholesterol** | **Permitted** | Maintaining cholesterol levels within the normal range is not considered a risk factor for disease and normal cholesterol considered important in maintaining a healthy body:<br>E.g., helps maintain cholesterol levels that are already in the normal range |
| | **Prohibited** | Claims that discuss lowering cholesterol levels and linked to treating high cholesterol levels and preventing heart disease<br>E.g., lowers cholesterol<br>E.g., promotes cholesterol clearance<br>E.g., healthy cholesterol (may be misleading because may be interpreted as referring to HDL) |

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|---|---|---|
| **Digestive Tract (stomach/ bowel)** | **Permitted** | Claims referring to conditions that have a variety of non-disease causes or conditions not sufficiently characteristic of specific diseases:<br>E.g., helps maintain regularity<br>E.g., helps maintain intestinal flora<br>E.g., relief of sour stomach<br>E.g., relief of upset stomach<br>E.g., laxative, relief of occasional constipation not intended to be used to treat chronic constipation<br>E.g., relief of occasional heartburn, occasional acid indigestion, if because of overindulgence or other sporadic situations<br>E.g., alleviates the symptom referred to as gas<br>E.g., alleviates bloating<br>E.g., alleviates pressure<br>E.g., alleviates fullness<br>E.g., alleviates stuffed feeling<br>E.g., for the prevention and treatment of nausea, vomiting or dizziness associated with motion<br>E.g., stool softener |
| | **Prohibited** | Conditions that only have disease causes or that can be signs of significant illness: ulcers; heals stomach or duodenal lesions and bleeding; relief of recurrent or persistent heartburn, acid indigestion, constipation, etc. |
| **Energy** | **Permitted** | E.g., boosts stamina |
| | **Prohibited** | |
| **Epilepsy** | **Permitted** | |
| | **Prohibited** | E.g., anticonvulsant |
| **Eyes, Nose and Throat** | **Permitted** | |
| | **Prohibited** | Claims for treatment for a characteristic symptom of colds, flu and hay fever:<br>E.g., relieve excessive secretions of the nose and eyes<br>E.g., nasal decongestant<br>E.g., bronchodilator<br>E.g., expectorant |
| **Heart** | **Permitted** | helps maintain cardiovascular function and healthy circulatory system |
| | **Prohibited** | Heart attack claims:<br>E.g., arrhythmia; prevents irregular heart beat<br>E.g., arteriosclerotic diseases of coronary, cerebral or peripheral blood vessels<br>E.g., inhibits platelet aggregation (therapy for the prevention of stroke and recurrent heart attack)<br>E.g., relieves chest pain |
| **Immune system** | **Permitted** | Claims not specific enough to imply disease prevention:<br>E.g., supports the immune system |
| | **Prohibited** | Disease-fighting claims or claims representing treatment or prevention of a specific class of diseases:<br>E.g., supports the body's antiviral capabilities<br>E.g., any reference to cold and flu season<br>E.g., AIDS; prevents wasting in persons with weakened immune system<br>E.g., infections: antibiotic |

| | | |
|---|---|---|
| **Intoxication** | | |
| | **Prohibited** | Claims regarding alcohol intoxication, which FDA considers a disease:<br>E.g., decreases the effects of alcohol intoxication |
| **Joint Function** | **Permitted** | Claims relating to maintaining normal joint function rather than treating joint pain:<br>E.g., helps support cartilage and joint function |
| | **Prohibited** | FDA considers joint pain a characteristic of arthritis and considers arthritis to be a disease:<br>E.g., reduces the pain and stiffness associated with arthritis<br>E.g., reduces joint inflammation and pain |
| **Lungs** | **Permitted** | E.g., maintains healthy lung function |
| | **Prohibited** | E.g., lung cancer or chronic lung disease; maintain healthy lungs in smokers |
| **Memory** | **Permitted** | Claims regarding absentmindedness; not considered to imply treatment of Alzheimer's disease because absentmindedness is not as serious as the type of memory loss characteristically suffered by Alzheimer's patients and is suffered predominantly by people who do not have Alzheimer's disease:<br>E.g., improves absentmindedness |
| | **Prohibited** | |
| **Menstruation** | **Permitted** | The menstrual cycle is considered a natural state and PMS generally is a common, mild associated condition:<br>E.g., mild mood changes, cramps and edema<br>E.g., supports a normal, healthy attitude during PMS |
| | **Prohibited** | Claims regarding severe depression associated with menstrual cycle |
| **Menopause** | **Permitted** | Menopause is considered a natural state and mild conditions commonly associated with the stage not considered disease:<br>E.g., hot flashes<br>E.g., supportive for menopausal women |
| | **Prohibited** | Osteoporosis claims |
| **Mood and stress** | **Permitted** | Claims regarding occasional stress and frustration because they are not considered characteristic symptoms of anxiety disorders and can be associated equally with non-disease states:<br>E.g., occasional simple nervous tension<br>E.g., nervous irritability<br>E.g., nervousness due to common everyday overwork and fatigue<br>E.g., gently soothe away the tension<br>E.g., calmative<br>E.g., helps you relax<br>E.g., resolving irritability that ruins your day<br>E.g., calming down and relaxing<br>E.g., a relaxed feeling<br>E.g., supports mood relaxation<br>E.g., promotes relaxation<br>E.g., reduces stress and frustration |
| | **Prohibited** | E.g., depression; herbal antidepressant<br>E.g., nervous tension headache (tension headache is considered a disease) |

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| **Muscle** | **Permitted** | Treatment and/or prevention of nocturnal leg muscle cramps<br>(FDA does not consider nocturnal leg cramps to meet the definition of disease):<br>E.g., helps increase muscle size<br>E.g., helps enhance muscle tone |
| | **Prohibited** | |
| **Osteoporosis** | **Permitted** | |
| | **Prohibited** | Any reference to osteoporosis:<br>E.g., prevents bone fragility in post-menopausal women<br>E.g., maintain normal bone density in post-menopausal women |
| **Pain** | **Permitted** | Minor pain relief claims without reference to any conditions, symptoms or part of the body implying disease treatment, or prevention of muscle pain after exercise |
| | **Prohibited** | |
| **Pregnancy**<br>[NOTE: FDA has advised dietary supplement manufacturers to refrain from pregnancy claims pending further agency consideration of safety concerns] | **Permitted**<br>(Subject to FDA Request for Moratorium) | Pregnancy considered natural state and mild conditions normally associated with the state not considered a disease:<br>E.g., morning sickness<br>E.g., leg edema |
| | **Prohibited** | Toxemia of pregnancy; Acute psychosis of pregnancy |
| **Sexual Function** | **Permitted** | Aphrodisiac claims:<br>E.g., arouses or increases sexual desire and improves sexual performance |
| | **Prohibited** | Impotence claims, references to potency:<br>E.g., restore potency, improve potency, etc., unless the claims made clear that they were intended solely for decreased sexual function associated with aging |
| **Sleep** | **Permitted** | Occasional sleeplessness is not a characteristic symptom of a disease:<br>E.g., for the relief of occasional sleeplessness |
| | **Prohibited** | Insomnia:<br>E.g., helps you fall asleep if you have difficulty falling asleep; helps reduce difficulty falling asleep |
| **Smoking** | **Permitted** | Smoking alternative, if the claim does not imply treatment of nicotine addiction, relief of nicotine withdrawal symptoms or prevention or mitigation of tobacco-related illness:<br>E.g., as a smoking alternative, temporarily reduces your desire to smoke<br>E.g., mimics the oral sensations of cigarette smoking<br>E.g., for short-term use in situations where smoking is prohibited or socially unacceptable |
| | **Prohibited** | Implying usefulness in treating nicotine addiction |
| **Stimulant** | **Permitted** | Occasional fatigue or drowsiness that is not a characteristic symptom of specific diseases:<br>E.g., helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness |
| | **Prohibited** | Chronic fatigue and narcolepsy |

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| **Urinary Tract** | **Permitted** | E.g., helps promote urinary tract health |
| | **Prohibited** | E.g., helps to maintain normal urine flow in men older than 50 years of age<br>E.g., deters bacteria from adhering to the walls of bladder and urinary tract<br>E.g., relieves symptoms of benign prostatic hypertrophy,<br>E.g., urinary urgency and frequency, excessive urinating at night, delayed urination |

### Third Party Literature

There is another way to convey valuable information about dietary supplements to your customers. Under DSHEA, publications written by third parties about the health benefits of dietary supplements may be distributed in connection with the sale of supplement products. This is so-called "third party literature."

Significantly, third party literature can lawfully discuss the role of dietary supplements in preventing or treating diseases, without subjecting the supplements to regulation by FDA as drugs. To do so, the publication involved must satisfy all the following conditions:

1. it must be a reprint of an entire article authored by someone other than the supplier or retailer;
2. it must be physically separate in a store or office from the product it describes;
3. it must present a balanced view of available scientific information about the supplement and its health benefits;
4. it cannot mention the name of a manufacturer or the brand name of a product; and
5. it cannot have any sticker or other information attached to it.

The obvious advantage to third party literature is that it can present health benefit information beyond structure/function claims, particularly statements about how a given dietary supplement can be useful in the prevention or treatment of some disease condition. Congress intentionally meant for consumers to have this type of information when it enacted the third-party literature section of DSHEA.

# Conclusion

Completion of this document does not make you a legal expert about dietary supplements. Rather, the intent has been to make you aware of some of the industry regulations surrounding your interactions with customers. Hopefully, you are now better prepared to keep your conversations with customers factual and legal. As always, if some of your clients/customers have a medical condition, it is imperative that they make their physician aware of all dietary and supplement changes that they decide to incorporate into their lifestyle.

## Multiple Choice Questions

1. If you wish to make a science-based recommendation for a dietary supplement, it must be based on more than having read an article in a magazine, or one or two personal testimonials.

   **a. True**

   b. False

2. A legal recommendation for a dietary supplement must avoid making the claim that the product will _____ a medical condition.

   a. prevent

   b. treat

   c. mitigate

   **d. all the above**

3. There are a few allowable health claims associated with dietary supplements. This includes claims for calcium, folic acid and _____.

   **a. soy protein**

   b. antioxidants

   c. Coenzyme Q10

   d. None of the above

4. "Supportive but not conclusive research shows that consumption of _____ may reduce the risk of coronary heart disease," is part of a qualified health claim for:

   a. phosphatidylserine

   b. calcium

   **c. EPA and DHA omega-3 fatty acids**

   d. folic acid

5. A structure/function claim for cancer is permissible if it specifies that the supplement is protective against the development of cancer, rather than stating that the product treats cancer.

   a. True

   **b. False**

6. All of the following are permitted structure/function claims for products formulated for the digestive system, EXCEPT:

   a. helps maintain regularity

   **b. heals stomach or duodenal lesions**

   c. alleviates bloating

   d. for the prevention and treatment of nausea, vomiting or dizziness associated with motion sickness

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