ROADMAP *for* RETAILERS

Safely Navigating What You Say About Dietary Supplements

Council for Responsible Nutrition
The Science Behind the Supplements®

www.crnusa.org

Consumers and supplements

Dietary supplements have long been considered an important component of a well-balanced health routine. Consumers take these products for broad health reasons—including filling nutrition gaps in their diets and maintaining overall health and wellness—and to support the healthy function of systems within the body, such as bone, joint, heart and digestive health. Many people are devoted to their supplements and believe them to be integral to their wellness pursuits.

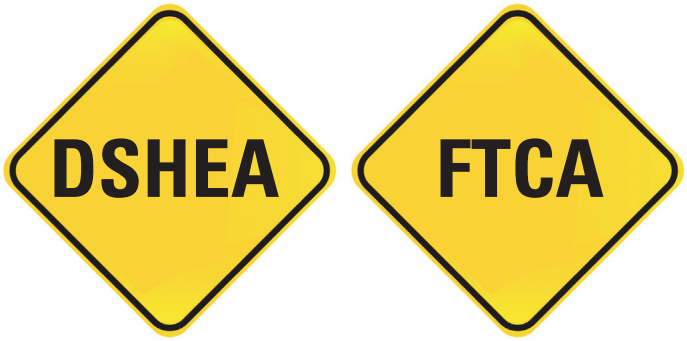
Consumers get information about dietary supplements from a variety of sources to help guide their purchasing decisions. Manufacturers and marketers of supplements are limited by law as to the claims they can make about their products on the labeling, in print or broadcast advertising, on their websites and in promotional literature. Similar requirements, restrictions and prohibitions also apply to retailers and distributors who speak directly with consumers. It is essential that individuals assisting consumers at the point of purchase discuss these products accurately and legally.

Retailer responsibilities

The responsibilities associated with making supplement claims are shared across the supply chain—it begins with scientists who evaluate scientific data, legal and regulatory experts who review potential claims, and finally, marketers who develop labels and marketing materials for a particular product. Once the product is in the retail environment for consumers to purchase, the responsibilities around making supplement claims continue to a retailer's comments when talking with consumers. The verbal interface which occurs at the point of sale is an important exchange because it helps guide consumers to the supplement products that are well suited for their individual needs.

Supplement laws

In the U.S., dietary supplements are regulated as a category of food by the Food and Drug Administration (FDA) under the Dietary Supplement Health & Education Act (DSHEA) of 1994[1]. FDA regulates the manufacturing facilities and labeling of dietary supplements. The Federal Trade Commission (FTC) regulates the marketing and advertising for these products under the Federal Trade Commission Act (FTCA)[2]. Together, these two separate laws require that all labeling and marketing claims for supplements are truthful and non-misleading and are scientifically substantiated. Further, dietary supplements cannot claim to treat, cure, mitigate, diagnose or prevent disease.



While assisting customers in their selections of dietary supplements, keep in mind to avoid offering medical advice or suggesting that supplements can treat a disease or replace prescription drugs.

If you are unclear about the best ways to discuss supplements with customers—all while staying compliant with existing FDA and FTC laws—this simple "road map" can help you navigate what you can say about dietary supplements to your customer.

Understand supplement regulations.

Because you are selling dietary supplements to the general public, it's important to learn how supplement claims are regulated. Understanding the law provides the foundation for knowing how to discuss supplement benefits and can give you confidence when talking with customers. Be aware of the kinds of claims manufacturers can make on labels, packaging, and advertising material, including those found on the internet. Always remember that advertising claims for dietary supplements are required to be truthful, not misleading and substantiated by credible scientific evidence, and cannot state or imply that supplements treat, cure, mitigate, diagnose or prevent disease. Claims made on the label of a dietary supplement product are regulated by the FDA[3].

Familiarize yourself with the supplement label.

Consumers use product labels to help understand what they are buying. Sales associates can best serve the customer by being familiar with what is on a supplement label. Recently, the Council for Responsible Nutrition (CRN) conducted a survey[4] of consumers to determine their usage and understanding of supplement products and found that the Supplements Fact Box (containing serving size, daily value, and ingredients among other things) and label claims (i.e. maintain heart health, maintain joint health) are among some of the most important factors for consumers when it comes to purchasing supplements. Understanding the label will better prepare you for questions regarding a particular supplement's ingredients, health benefits, daily intakes, etc.

Helping consumers understand the information found on the label is one of the most important roles of a retail associate. CRN has a sample interactive label located on its website.

Supplement Facts

Serving Size 1 tablet

Suggested Use: Adults, take one tablet per day with meal

Amount Per Serving	% Daily Value
Vitamin A 5000 I.U.	
50% as Beta Carotene	100%
Vitamin C 250 mg	417%
Vitamin D 400 I.U.	100%
Vitamin E 200 I.U.	667%
Vitamin K 80 mcg	100%
Thiamin 5 mg	333%
Riboflavin 5 mg	294%
Niacin 20 mg	100%
Vitamin B_6 5 mg	250%
Folic acid 400 mcg	100%
Vitamin B_{12} 6 mcg	100%
Biotin 150 mcg	50%
Pantothenic Acid 10 mg	100%
Calcium 200 mg	20%
Iron 18 mg	100%
Phosphorus 200 mg	20%
Iodine 150 mcg	100%
Selenium 35 mcg	50%
Magnesium 200 mg	50%
Zinc 15 mg	100%
Copper 2 mg	100%
Boron 150 mcg	*

* Daily Value not established

Ingredients: vitamin A acetate, beta carotene, vitamin D, dl-alpha tocopherol acetate, ascorbic acid, thiamin mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, vitamin B12, biotin, d-calcium pantothenate, potassium chloride, dicalcium phosphate, potassium iodine, ferrous fumarate, magnesium oxide, copper sulfate, zinc oxide, manganese sulfate, sodium selenate, chromium chloride, sodium molybdate, microcrystalline cellulose, calcium carbonate, sodium carboxymethyl cellulose

Storage: Keep tightly closed in dry place; do not expose to excessive heat

KEEP OUT OF REACH OF CHILDREN

Expiration date: JUN 2013

Company V, Cityville, New York 01010

Promote the consumer/healthcare practitioner dialogue.

Consumers should get health advice from their doctor or other healthcare professional. As the retailer, you are there to guide customers in their supplement options, not to offer medical advice. In fact, it is illegal to give medical advice without the appropriate medical license. While you may feel enthusiastic about a particular supplement, you must remember that when selling supplements, your eagerness must be limited to what you can say under the law.

A healthcare practitioner is appropriately trained to diagnose specific conditions and diseases and give consumers medical advice. Consumers should already be updating their physician (and other healthcare professionals such as nurse practitioners, registered dietitians, etc.) about the supplements they are taking or considering. If a customer describes symptoms to a health-related concern, don't provide your diagnosis for what ails him. Unless you have a license to practice medicine, don't give medical advice.

Likewise don't recommend supplements as an alternative or replacement for their prescription medications. Only the licensed practitioner who authorized their prescription should tell them when and whether to take it.

It's responsible to encourage your customers to have an open dialogue with their healthcare practitioner about the supplements they take, and it demonstrates that you are putting the consumer first when you do.

Help educate your customer.

Consumers can be confused and overwhelmed by the number of options available when choosing a dietary supplement. It is best to start with the basics—after the customer has had a consultation with a medical professional, determine what best makes sense for an individual's lifestyle/life stage, dietary needs, etc., and then go with a brand that is well-established, a brand that they know and trust. A customer looking for more information than what is found on the product's label or in the manufacturer's promotional material can be referred to other third party literature that meets specific standards set forth by the law. DSHEA outlines specific criteria that allow some dietary supplement educational material to be considered "third party literature," meaning it is exempt from the same kinds of limitations that are in place for product labels and other promotional material.

To be considered "third party literature," it must satisfy the following criteria[5]:

a. Literature is not false or misleading;
b. Literature must be displayed in an area physically separate from the dietary supplements;
c. Literature must present a balanced view of available scientific information on a dietary supplement and its health benefits;
d. Literature cannot mention the name of a particular manufacturer or the brand name of a dietary supplement; and
e. Literature cannot be modified by a sticker or have any other information attached to it.

Examples of third-party literature include references from an in-store computer kiosk, scientific journal articles, books, and other printed material. Third-party literature is an excellent resource for knowledge-seeking consumers.

Regarding education, it's also a good idea to frequently update your own training. Take advantage of company training programs, trade association workshops, and other industry educational efforts so that you are aware of emerging science and revised policy and regulatory matters. Trade shows, webinars, and other interactive programs provide ongoing support to optimize staff training, while minimizing risks associated with non-compliant advertising.

Be careful of testimonials.

Often, you may want to share the experiences of other customers with a new customer, or talk about a family member or friend who had a great experience with a particular product, or even a celebrity you have heard uses that product with great results. Be careful: the FTC's position is that promoting another person's experience with a product is essentially a claim for the product (a "testimonial"). Unless that experience is likely to be the typical experience of a user, you should refrain from discussing the testimonial, or at the very least, also tell the customer what the results of a typical person will be. Just because your neighbor lost 30 pounds and is now training for a marathon since using the product, it doesn't mean everyone will have the same experience. Note the FTC recently tightened its standards for testimonials[6]: simply saying that "results may vary" is not enough, and the person communicating the testimonial can be held liable for false, misleading, or otherwise unlawful statements. If you use a testimonial from someone else's experience to promote a product, then you are expected to know and disclose what the average or typical consumer can expect.

Despite these words of caution, don't feel overwhelmed when it comes to what you can and can't say about dietary supplements. Take every opportunity to learn more about these valued products and keep in mind that the responsibility of appropriate supplement marketing is not limited to what you see in marketing materials or in television advertising. Everyone involved with the sale of supplements shares the responsibility to ensure that the most accurate (and helpful) information reaches our consumers.

Three basic types of legal claims are permitted on the bottle:

1) **Nutrient content claims** to characterize the level of vitamins and minerals in the product (e.g., "a good source of Vitamin C," or "high in antioxidants"). Consumers are often confused by Recommended Daily Allowances (RDAs), serving units, and standard measurements (mg, mcg, I.U.). You can educate them, help them compare products and select ones that best meet their needs.

2) **Structure/function claims** to describe the basic benefits of the product on a particular structure or function in the body (e.g., "helps support healthy joints," "maintain strong bones,"); and

3) **FDA-approved health claims or qualified health claims** that describe the relationship between a substance and reduced risk of a disease (such as calcium and vitamin D in relation to osteoporosis). Unlike nutrient content claims and structure/function claims, FDA must review the evidence for a health claim and approve its use. Note that FDA maintains a distinction between "reducing the risk" of a disease, which it views as an appropriate health claim for supplements if approved by the agency, and "prevents" disease, which it views as a disease claim that can only be made by an approved drug.

A simple rule of thumb would be to limit your discussions about a product's benefits to what is listed on the label or in the manufacturer's printed material. The language used there should already be within the scope of the law and should have been substantiated with credible scientific evidence by the product's manufacturer/marketer.

DO:

- **Stick to the claims in the manufacturer's written materials.**
- **Discuss ingredient content of products, as provided on their labels.**
- **Discuss structure/function claims based on the claims on the label.**
- **Stick with only those health claims that are on the product (i.e., "reduces the risk of …").**
- **Suggest customers talk to a healthcare professional for diagnosis and treatment options.**

DON'T:

- **Claim the product can treat, cure, mitigate, diagnose or prevent disease.**
- **Instruct customers regarding prescription drug use unless you are a qualified healthcare professional.**
- **Offer advice about drug-supplement interactions (or lack thereof) unless you are a trained healthcare professional.**
- **Practice medicine, nursing or dietetics (or any other medical specialty) without a license —don't diagnose.**
- **Don't use testimonials unless they are typical of what consumers can expect or they are properly qualified as required by law.**

Glossary of terms used in this brochure:

Council for Responsible Nutrition (CRN) – founded in 1973 and based in Washington, D.C., CRN is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our members also agree to adhere to voluntary guidelines for manufacturing and marketing of dietary supplements as well as CRN's Code of Ethics.

Dietary supplement – a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet.

Dietary Supplement Health & Education Act (DSHEA) – the 1994 law that amended the federal Food, Drug & Cosmetic Act to provide a regulatory category for dietary supplements. It provided a definition of the dietary supplement category and created new requirements and restrictions unique to these products. DSHEA allows manufacturers and retailers to make certain claims about supplements and places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement.

Disease claim – a statement that a product can prevent, treat, cure or mitigate a disease or the symptoms of a disease. Dietary supplements are not permitted to make disease claims.

Health Claim – a statement that describes the relationship between a substance and a disease in the labeling of foods, including dietary supplements. An authorized health claim may be used on both conventional foods and dietary supplements, provided that the substance in the product and the product itself meet the appropriate standards in the authorizing regulation. Health claims are directed to the general population or designated subgroups (e.g., the elderly) and are intended to assist the consumer in maintaining healthful dietary practices. Health claims require the approval of FDA for the claim.

Nutrient Content claim – a statement that characterizes the level of vitamins and minerals in a product.

Qualified Health Claim – a statement that describes the relationship between a substance and a disease but for which there is not significant scientific agreement. A qualified health claim requires the approval of FDA for its use and must properly explain or "qualify" the statement in light of the available scientific research.

Structure/function claims – a statement that describes the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans. A structure/function claim may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function or it may describe general well-being from consumption of a nutrient or dietary ingredient.

Substantiated – the necessary support to make an advertising or labeling claim that is not false or misleading to consumers. Both the FDA and the FTC have well-documented requirements for the level of credible scientific evidence that is necessary to properly support, or substantiate, a claim for a dietary supplement.

Testimonial – a testimonial or endorsement means any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.

Third Party Literature – materials that describe the benefits and safety of a dietary supplement that were not prepared by the manufacturer or marketer of the product. Third party literature is exempt from many of the restrictions and requirements for labeling and advertising claims, but it must satisfy certain criteria illustrating its objective, balanced nature; it may not refer to a particular brand name; and it may not be displayed in the same physical part of the store as the supplements to which it refers.

Footnotes

1 Food and Drug Administration (FDA) Regulation of dietary supplements: http://www.fda.gov/food/dietarysupplements/default.htm

2 Application of FTC law to dietary supplement advertising: http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry

3 Claims That Can Be Made for Conventional Foods and Dietary Supplements: http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm111447.htm

4 2010 CRN Consumer Survey on Dietary Supplements, Council for Responsible Nutrition, conducted among U.S. adults by Ipsos Public Affairs, August-September 2010

5 Dietary Supplement Health and Education Act of 1994. Public Law 103-417. 103rd Congress: http://ods.od.nih.gov/About/DSHEA_Wording.aspx

6 Federal Trade Commission. 16 CFR Part 255. Guides Concerning the Use of Endorsements and Testimonials in Advertising: http://www.ftc.gov/os/2009/10/091005revisedendorsementguides.pdf

This document was prepared by the Council for Responsible Nutrition (CRN), the leading trade association representing dietary supplement manufacturers and ingredient suppliers, to assist its members, their customers, and other retailers selling dietary supplements with meeting their obligations under the law. This material is not a substitute for legal advice regarding the specific claims for individual products and ingredients. Companies should consult their legal counsel for tailored advice on the permissibility of a specific claim. For more information, visit www.crnusa.org.