

DSHEA

The Dietary Supplement Health and Education Act

Frequently Asked Questions

Like most retailers, you want to help customers make informed decisions about what dietary supplements best meet their needs. However, there are restrictions on the types of information you can share with customers online or in store based on DSHEA regulations.

DSHEA clearly defines what can and can't be said in connection with the sale of dietary supplements, making it imperative that retailers understand the law's ins and outs, as well as how certain third-party solutions, like Aisle7[®] products, can help you lawfully educate customers.

What Is DSHEA?

As the health food industry rapidly grew in the 1970s and 80s, conflicts increased between manufacturers and the US Food and Drug Administration (FDA), as the agency asserted many dietary supplements were either unapproved food additives or unapproved drugs and not foods.

DSHEA was passed in 1994 in response to support from individual citizens as well as the dietary supplement industry. Its passage established a class of ingredients as dietary supplements, removing them from the categories of drugs and food additives, and creating a new regulatory framework for supplements. It clearly distinguishes supplements from pharmaceuticals and defines the type of health benefit claims that can be made.

DSHEA creates a framework for the regulation of dietary supplements as follows:

- 1. Definition**—Dietary supplements are defined as products intended to supplement the diet that contain vitamins, minerals, herbs, amino acids, or other dietary ingredients, as well as concentrates, extracts, or any combination of these types of ingredients. They may be offered in a wide range of forms (capsules, tablets, liquids, powders, bars, etc.) but may not be represented for use as a conventional food. They must be labeled with the words “dietary supplement” or a synonym such as “herbal supplement” or “vitamin supplement.”
- 2. Safety Standards**—Dietary supplements are considered unsafe if they present an unreasonable risk of illness or injury under the conditions of use recommended on the label. Manufacturers are encouraged to add appropriate warnings, cautions, and dosage limits to labels, such as advisories to pregnant or lactating women, instructions to keep out of the reach of children, etc. Each company must determine appropriate usage and provide directions for the safe use of its products on labeling and conform to published FDA “Current Good Manufacturing Practices” (CGMPs).

3. *Use of Health-Related Literature*—DSHEA also allowed for education, by allowing consumers to learn about dietary supplements via “third-party literature.” This provision allows a broad range of information (including publications, articles, book chapters, and abstracts of scientific publications) to be used by retailers in connection with dietary supplement sales. This exemption creates a “church and state” division, stating content cannot promote a particular brand, must not be false or misleading, and must be physically separate from the product.

4. *Statements of Nutritional Support*—DSHEA created a new class of claims called statements of nutritional support, commonly known as structure/function claims, which are different than health claims and may appear on dietary supplement product labels, promotional materials, advertising, or websites. Companies making these statements must include a disclaimer, prominently displayed, stating: *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.*

Structure/Function Claims may:

- describe how nutrients or dietary ingredients affect the structure or function of the body,
- characterize the documented mechanism by which a dietary ingredient maintains body structures or functions, or
- describe general well-being from consuming dietary supplements.

Sample Structure/Function Claims:

- Helps promote restful sleep (valerian or melatonin).
- Supports the immune system (echinacea or vitamin C).
- Helps maintain cardiovascular health (vitamin E).

How Does DSHEA Apply to Retailers?

Retailers are in a prime position to provide information to customers on the products they sell. This is good for customers and good for retailers. However, retailers and most store employees (pharmacists excluded) are unable to diagnose symptoms or prescribe a regimen of supplement use. DSHEA’s Third-Party Literature provision allows retailers the opportunity to help customers find information in conjunction with the sale of a dietary supplement.

How Can Retailers Stay DSHEA Compliant?

Retailers can protect themselves against DSHEA violations by establishing a science-based, balanced, and reliable third-party education resource like Aisle7 In-Store™ or Aisle7 Online™ to educate customers and answer their questions. Important to this equation is implementing a lightweight yet effective process by which store staff use Aisle7 products to provide high degrees of service while staying within the boundaries of the law.

What Constitutes Third-Party Literature?

Section 5 of DSHEA addresses “Dietary Supplement Labeling Exemptions,” specifically Section 403B, which allows for third-party literature in order to:

1. meet the objectives of those who want to provide educational literature about products and nutrients, and
2. specifically state publications, as defined below, shall not be defined as labeling.

DSHEA allows a broad range of information, including publications, articles, book chapters, and abstracts of scientific publications, to be used “in connection with the sale of dietary supplements” as long as the information meets the following requirements:

- It is not false or misleading.
- It doesn’t promote a particular manufacturer or brand.
- It is **balanced** (meaning it presents the pros and cons, the state of the science, and its summary says where the science stands).
- It is kept **physically separate from the product**.
- There are no company identification stickers or stamps applied to it.
- It **uses official abstracts** of single studies, or summarizes a group of studies.

What You *Can* Say to Customers

- You **can** refer customers to information such as that found in Aisle7 products. Nutritional information in Aisle7 products has been carefully designed to meet the standards for third-party literature specified in DSHEA. It is balanced, referenced, footnoted, and non-branded.
- You **can** verbally repeat the structure/function claims or the general statements of well-being on the product label or labeling.
- You **can** provide general information about the importance of diet and exercise for a healthy lifestyle. Encourage customers to eat their veggies and move their bodies for overall health.
- You **can** provide third-party literature (Aisle7 content, books, journals, newsletters) as information sources.
- You **should** always recommend customers seek the advice of a licensed healthcare professional.

What You *Cannot* Say to Customers

- **Do not** diagnose customers' conditions based on their symptoms or your personal health experience. Help customers look up concerns in the Aisle7 database for further research.
- **Do not** imply a dietary supplement will cure or treat a specific disease, even if you know the product is sold as a pharmaceutical medication in another country. Look up the supplement in the Aisle7 database and share the overview of scientifically validated uses.

- **Do not** recommend a dosage or daily intake greater than that recommended on the product label. Aisle7 content provides dosage amounts based on the latest science, which can serve as a resource if this question arises in a customer conversation.
- **Do not** suggest dietary supplements should be used to replace conventional treatments or medications. This is a conversation that should happen between the customer and their physician.
- **Do not** recommend specific alternative treatments in place of conventional therapies.

What's the Best Way to Remember DSHEA for a Retail Setting?

When a customer asks you a health question, follow the 4S model.

- **Science**—Use a reference source like Aisle7 In-Store to relate the science behind a specific nutrient or ingredient.
- **Safety**—Find out if they are taking medicines. If so, reference Drug–Nutrient Interactions in Aisle7 RxAnswers.
- **Service**—Show your customer where the products are in the store.
- **Sell**—Provide guidance on manufacturers and value based on your customers' needs.

These rules are meant to protect you and the company you work for. We encourage you to use high-quality resources like Aisle7 products to learn more about supplements so you are well informed about the products your store carries. And keep in mind that everyone involved with the sale of supplements (from the manufacturer to the store staff) shares in the responsibility of providing customers with the most accurate and helpful research available.