

This section of the textbook discusses the major nonprescription therapies considered by women at menopause and beyond, including vitamins and minerals, other nonbotanical dietary supplements available over the counter (OTC), vaginal lubricants and moisturizers, and topical agents used for sexual pleasure. Botanical supplements are discussed in Section I.

NAMS recommends use of some of these nonprescription therapies, when indicated, with appropriate oversight from a healthcare provider. However, the public frequently self-medicates with little guidance or knowledge of the efficacy and safety of the products they use. Few OTC therapies have patient package inserts (user information sheets that explain the evidence for the claimed efficacy and safety of the product). This document, required by the US Food and Drug Administration (FDA) for all marketed prescription medications, provides vital information on how to take a drug safely, identify its negative side effects, and avoid potentially dangerous interactions with other drugs.

Safety may not be mentioned at all in a nonprescription product's advertising or label, although the word "natural" is often seen, and is often misinterpreted by the public as being without risk of adverse effects. In addition, dietary supplements—a common type of OTC therapy—are government regulated in the United States and Canada differently from prescription drugs with regard to allowed health claims, causing confusion among the public and sometimes healthcare providers as well. Thus, OTC therapies present challenges to the menopausal woman and her healthcare providers.

NAMS understands that nonprescription therapies have not been proven to be as effective as prescription therapies when treating certain health conditions. Yet, since the basic tenet of the Hippocratic Oath is to do no harm and nonpharmacologic treatments typically do little harm, NAMS often suggests nonpharmacologic treatments as "first-line" treatments as they have the least risk.

Government regulations for dietary supplements

This section of the textbook presents the current government regulations for dietary supplements in the United States and Canada—essential information for both the healthcare provider and the public.

Terminology. In the United States, the term *dietary supplement* includes OTC vitamins, minerals, amino acids, enzymes, herbs, plants in various forms (such as extracts), and combinations intended for ingestion as an addition to the diet. In the United States, according to the 1994 Dietary Supplement Health and Education Act (DSHEA), a dietary supplement is defined as a pill, capsule, tablet, or liquid that contains a "dietary ingredient." However, other products that are not ingested also fall within the dietary supplement guidelines (eg, topical progesterone cream).

In Canada, the term *natural health product* (NHP) is used in place of dietary supplement as defined by the Natural Health Products Regulations, which came into effect in 2004. NHPs include vitamins and minerals, probiotics, and other products such as amino acids and essential fatty acids. Also classified as NHPs are herbal products, homeopathic medicines, and traditional medicines such as Traditional Chinese Medicine (see Section I for more about complementary and alternative medicine [CAM] therapies).

United States. In the United States, government regulations regarding whether a dietary supplement is effective and safe are less strict than those for prescription drugs. Under the DSHEA, the manufacturer (not the FDA) is responsible for determining that any representations or claims made about its products are substantiated by adequate evidence to show that they are not false or misleading. Dietary supplement marketers can make health claims for so-called "natural conditions" (eg, hot flashes, age-related memory loss) without providing documentation for efficacy and safety to the government. However, they cannot claim that a product prevents, treats, or cures a disease (eg, prevents heart attacks or osteoporosis, cures depression) unless the FDA approves the claim.

DSHEA further states that the manufacturer (not the FDA) is responsible for ensuring that labels on packages of dietary supplements are truthful and not misleading, that they contain enough information for consumers to make an informed choice, that the serving size ("dose") is appropriate, and that all the dietary ingredients in the product are accurately listed.

Demonstrating safety is not required before a dietary supplement is approved for sale. Under DSHEA, dietary supplement manufacturers are responsible for substantiating the safety of the ingredients used in a product. The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. This regulatory agency accomplishes its responsibilities through monitoring safety literature, dietary supplement adverse-event reports, and product information.

Although many manufacturers have rigorous quality control measures in place, many products are not monitored for purity or level of active ingredient. As a result, strength and quality can be unpredictable. If a product is suspected of causing harm, the FDA can halt sales and have it analyzed.

Botanicals (eg, soy, isoflavones, black cohosh) are classified by the FDA as a food, drug, or dietary supplement (see Section I for more about CAM therapies). There are numerous quality control concerns with some botanicals, including misidentification, "underlabeling" (ie, including prescription drugs in OTC products), adulteration, substitution, and contamination. In addition, analytic-method standards are lacking for many products, leading to difficulty when attempting to assess product quality.