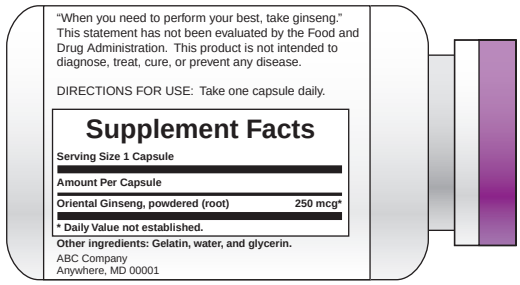

FIGURE 3.9 Example dietary supplement label.

or diagnose a disease. Thus, "structure/function" claims are allowed on the label. An example would be a claim that a product helps "improve mood" rather than treat depression. Statements can also be made relative to classical dietary nutrient deficiency disease and state of the prevalence of the disease in the United States.

In those instances when a manufacturer makes a permissible claim, the label must also bear the disclaimer, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." For herbal products, the label must also state the part of the plant used to make the product, for example, root, stem, or leaf. A standardized format provides the patient with certain minimum information about the product prior to its use. See Figure 3.9 for an example.

In 2009, the U.S. Pharmacopeial Convention initiated publication of the USP Dietary Supplements Compendium (DSC), a collection of standards designed to assist dietary supplement manufacturers in providing quality products to consumers. The DSC contains quality specifications for the identity, strength, purity, and performance characteristics (e.g., dissolution, disintegration) of dietary supplements included in the monographs. It also includes general and regulatory information and guidance to help manufacturers comply with FDA's cGMPs. Since its first publication, the DSC has been expanded and continually updated (23).

The USP also offers *verification services* for dietary supplement finished products and the ingredients used to make them. Products and ingredients that meet all USP verification requirements—including a GMP audit, product and ingredient testing, and manufacturing documentation review—are awarded use of a distinctive "USP Verified Mark" or logo, which may be displayed on product labeling. Participation is voluntary.

Storage

To ensure the stability of a pharmaceutical preparation for the period of its intended shelf life, the product must be stored in proper conditions. The labeling of each product includes the desired conditions of storage. The terms generally employed in such labeling have meanings defined by the USP (12):

> Cold: Any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2°C and 8°C (36°F and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between – 25°C and – 10°C (– 13°F and 14°F).
>
> Cool: Any temperature between 8°C and 15°C (46°F and 59°F). An article for which storage in a cool place is directed may alternatively be stored in a refrigerator unless otherwise specified in the individual monograph.
>
> Room temperature: The temperature prevailing in a working area. A controlled room temperature encompasses the usual working environment of 20°C to 25°C (68°F to 77°F) but also allows for temperature variations between 15°C and 30°C (59°F and 86°F) that may be found in pharmacies, hospitals, and drug warehouses.
>
> Warm: Any temperature between 30°C and 40°C (86°F and 104°F).
>
> Excessive heat: Above 40°C (104°F).
>
> Protection from freezing: Where in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency or to destructive alteration of the dosage form, the container label bears an appropriate instruction to protect the product from freezing.

Transportation

The stability protection of a pharmaceutical product during transportation is an important consideration. Temperature and humidity variations may occur during shipment from a manufacturer to a wholesaler or to a pharmacy and from a pharmacy to a patient, during mail order shipment of prescriptions and their time in the mailbox, and in emergency care vehicles. Transportation to and within geographic areas of extreme temperatures and humidity requires special consideration.